THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	January 3, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of January 3, 2013
Members Present:	Drs. Adam Clore, Paul Cooper, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Michael Pentella and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Leonard Duncan and Jeffery Meier
Guest Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on December 20 2012**
   No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Ms. McGhan, to approve the minutes of the December 20, 2012, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following nine rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	N. Spencer	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Smith	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Domann	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Roller	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Hostager	[redacted]

- [redacted]

[redacted]

[redacted]

- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wilson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Lee	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Meier	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Lubaroff	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

3. **Old Business**

a) Additional information was provided to the committee by Dr. White regarding the request of Dr. Ibrahim Ozobolat (Department of Mechanical and Industrial Engineering) to use a bioprinter in a vertical laminar flow clean bench rather than in a biosafety cabinet (BSC). The PI has proposed that he move the printer into the BSC when human cells are used and subsequently decontaminate the outer portion of the printer with UV light and ethanol. The syringes and inner tubing are disposable and would be disposed of in a biohazardous waste container. Following decontamination of the printer and disposal of the syringes and inner tubing, the printer will be moved from the BSC to the clean bench for use with animal cells. The preparation of all cell samples and loading of syringes will be done in the BSC.

The committee asked about the size of the printer and if it likely will affect the airflow in the BSC adversely. Prior to the meeting Dr. White attempted to contact the technical manager at ENV to address this question but was unable to obtain a response. The printer is not a solid piece of equipment, but rather has an open structure which likely would allow ample airflow around it and not interfere with the containment provided by the cabinet. Dr. White will work with the PI to ensure that, prior to use of the printer with human cells inside the BSC, airflow testing is performed by the ENV technician to establish that when the printer is inside the BSC airflows are not affected adversely. The PI is aware of the annual certification requirement of the BSC.

No further concerns were raised by committee members regarding the use of the bioprinter in the BSC when human cells are used assuming that it is established that the airflow of the BSC provides appropriate containment and the PI follows the procedures outlined here.

4. **New Business**

a) Dr. Sinn reported on one amendment to a previously-approved rDNARD that was approved by Dr. Dr. Sinn since the last meeting.
   - Dr. Lentz, #120262 was amended to include an additional staff member.

b) Dr. Sinn informed the committee tha[redacted]n was completed at th[redacted] last month and that the report will be sent out to committee members following this meeting.

c) Dr. Kirchhoff reported on his recent efforts to ensure that all non-exempt rDNA research being conducted at the UI is reviewed and approved by the IBC as required under the *NIH Guidelines*. Currently, the University has a two-tier system under which research involving rDNA is either registered and approved by the IBC or deemed exempt from registration under the *NIH Guidelines*. Prompted by a PI's recent uninformed and baseless claim that his rDNA research was exempt from registration, Dr. Kirchhoff conducted telephone interviews with six PIs whose claims for exemptions from the requirement for registration had been accepted by EHS in the past and who did not have active IBC-approved rDNARDs. Only one of the six PIs interviewed was able to provide appropriate justification for the exemption based on the narrow provisions in the *NIH Guidelines* that relate to exemptions and thus appeared to be in compliance. The other five PIs were unable to provide justification for their exemptions based on the relevant provisions in the *NIH Guidelines* and thus appeared to be non-compliant either in the past or currently.

Subsequent to Dr. Kirchhoff's telephone interviews with the PIs, Dr. Walker held a meeting with Drs. Sinn, White, and Kirchhoff, as well as Ms. McGhan, to discuss how best to eliminate instances of non-compliance resulting from inappropriate claims for exemptions from the requirement for registration. A basic problem in the current process for exemptions is the conflict of interest inherent in allowing PIs to make the determinations that their rDNA research is exempt. The possibility of developing a more rigorous administrative procedure for processing requests for exemptions that would ensure compliance was discussed at length. The group concluded that a procedure for processing and monitoring exemptions that would ensure compliance with the *NIH*

Guidelines would require as much, if not more, work for both the PIs and EHS staff as would registering the proposed rDNA experiments through the usual process. Having reached this conclusion, and also considering the fact that requests for exemptions from the requirement for registration are quite rare, is was decided unanimously that the option of obtaining exemptions from registration of proposed experiments involving rDNA should be eliminated. The group felt that moving to a single-tier system under which PIs would have to register all proposed rDNA research through the smoothly-functioning electronic system maintained by EHS would be administratively less onerous for all parties involved and at the same time ensure compliance with the *NIH Guidelines*

Committee members were asked to consider this proposal for further discussion at our next meeting. Any questions should be addressed to Dr. Kirchhoff or Biosafety Staff.

The next meeting will be held at 3:30 p.m. on January 17, 2013.

The meeting adjourned at 4:05 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
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Date: January 17, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 17, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Jeffery Meier, Michael Pentella and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan, Maria Martino-Cardona and Haley Sinn

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 3 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Ms. McGhan, to approve the minutes of the January 3, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following nine rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Weigel	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Spitz	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wilson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Lubaroff	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

Dr. Jones joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
[redacted]	E. Fuentes	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Russell	[redacted]

- [redacted].

[redacted]

- [redacted]
- [redacted]
- [redacted].

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted].
- [redacted].
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Amendt	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Burnett	[redacted]

[redacted]

The second part of the meeting was open to the public.

3. ***Old Business***

a) Dr. Kirchhoff summarized the issues relating to the proposal he presented to the IBC at its last meeting, under which all experiments involving rDNA, including experiments exempt from registration under the *NIH Guidelines*, would have to go through the IBC's registration and approval process. Dr. Jones voiced his general concern about the increasing amount of time PIs have to spend dealing with regulatory requirements and also stated his expectation that the adoption of the proposed single-tier system would further increase this burden for PIs doing exempt rDNA work. In response, Dr. Kirchhoff explained that since almost all of the PIs he contacted who had obtained exemptions from registration currently were or had been noncompliant with the *NIH Guidelines,* a more rigorous procedure for processing PI requests for exemptions would have to be developed to ensure compliance. He further stated that such an expanded process for review of requests for exemptions would involve more administrative time on the part of the PIs and also would involve an increased burden for EHS staff. Ms. McGhan stated her agreement with this latter perspective and mentioned that information presented at meetings of the American Biological Safety Association (ABSA) and discussions with counterparts at other academic institutions indicate that roughly half of them have single-tier systems such as that proposed. She and Dr. Kirchhoff reiterated the fact that only a very small number of PIs currently are doing exempt rDNA research. Ms. McGhan then further explained that EHS staff expect that moving to a single-tier system under which PIs would have to register all proposed rDNA research through the electronic system maintained by EHS would be administratively simpler for PIs and at the same time ensure compliance with the *NIH Guidelines.*

Dr. Kirchhoff summarized the changes in the UI's processes and documents that would have to be made following the IBC's approval of the single-tier proposal:

- Revision of the routing form to remove the question that asks if the proposed rDNA work is exempt from the *NIH Guidelines*, in addition to revision of the letter that is generated in response to an indication that the proposed work involves rDNA or synthetic nucleic acids;
- Revision the annual EHS audit form;
- Notification through email to all PIs of this change, explaining that it will ensure compliance with the *NIH Guidelines* and reduce the time required for PIs to obtain approval for their proposed rDNA work;
- Publishing an article in the *EHS LabNews* that explains the change in procedure;
- Revision of the rDNA training course;
- Revision of the rDNA manual; and
- Revision of the IBC SOP

Dr. Clore made a motion, seconded by Dr. Meier, to require that all work with rDNA and synthetic nucleic acids be registered with the IBC, even that which is considered exempt from registration under the *NIH Guidelines*.

b) Ms. Kratz provided additional information or clarification that was received from the PI regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Sigmund, #120318, clarified that AAV work is not part of this protocol.
- Dr. Legge, #120319 provided his staffs' experience working with the virus and rDNA, added vaccinia and listeria as hosts to the table and removed vaccinia strain PPL-2.
- Dr. Domann, #120329, confirmed that Ad-CMV is a shuttle plasmid, not a viral vector and also that this work will be done in *E coli* at BSL1.
- Dr. Lee, #120341, added the suggested antibiotic gene blasticidin.

4. **New Business**

a) Ms. McGhan reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff since the last meeting.

- Dr. Perlman, #110088 was amended to include an additional staff member additional inserts to the SARS-CoV work he's doing in BSL3 (which includes monkey cell lines and mice), and added work with vaccinia virus (WR) strain in rabbit cell lines and mice.
- Dr. Erives, #130102 was amended to add addition vectors, e.g., pBluescript and similar vectors into Drosophila – all at BSL1.
- Dr. Lalumière, #100138 was amended to include additional inserts (ASIC 1a and GFP) for his approved work with AAV in rats.
- Dr. Davidson, #100173, was amended to include the Rheb gene as an insert to her extensive list of inserts used with plasmid and viral work that is done in cell lines, animals, and *E coli.*
- Dr. Kirby, #110067 was amended to include inserts from *Staphylococcus aureus* and *S. aureus* as a host, along with adding staff.

b) Registration of rDNA projects at the Transgenic and Genome Manipulation Core (combined Transgenic and Knockout cores)

Dr. Phillip Sanford, director of the new Transgenic and Genome Manipulation Core would like to have blanket approval to perform specific work in the core. He provided Dr. White with a list of four types of projects that he would like to have included under such blanket approval, and Dr. White summarized the projects for the IBC. Dr. Kirchhoff requested that Dr. White work with Dr. Sanford to refine his proposal such that it is a formal request that succinctly states what his proposal is and what work would be excluded. Dr. White will present Dr. Sanford's revised proposal at a future IBC meeting.

The next meeting will be held at 3:30 p.m. on January 31, 2013.

The meeting adjourned at 4:27 p.m.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

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Environmental Health & Safety
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Ph. 319-335-8501
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Date: January 31, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 31, 2013

Members Present: Drs. Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Michael Pentella, Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 17, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the January 17, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Milhem	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Soll	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Soll	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Janz	[redacted]

[redacted]

Dr. Pentella joined the meeting at this time.

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	M. Blumberg	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	S. Janz	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	A. Mark	[redacted]

- [redacted]

[redacted]

- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	L-S. Song	[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
[redacted]t.
[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	T. Starner	[redacted] [redacted]s

- [redacted].
[redacted]
- [redacted]
[redacted]t.
[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) Dr. Sinn provided additional information or clarification that was received from the PI regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Fuentes, #120348, clarified that retroviral vectors are gag/pol/env deleted and pCMV is an expression vector with a CMV promoter.

4. **New Business**

a) Dr. Sinn reported on eight amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff since the last meeting.

- Dr. Maury, #120060 was amended to include Dr. Chioma Okeoma as a Co-PI and two of her post-doc fellows as staff, an adenoviral shuttle vector and additional inserts including glycoproteins, annexinV, a protein that plays a role in blood coagulation, and versican, an extracellular matrix proteoglycan that may play a role in Ebola virus glycoprotein dependent entry.
- Dr. Perlman, #110088 was amended to include IN as a route of administration for vaccinia virus.
- Dr. Sigmund, #120318 was amended to include LacZ as an insert.
- Dr. Sigmund, #100111, was amended to include SQ as a route of administration.
- Dr. Legge, #120319 was amended to include IM as a route of administration.
- Dr. O'Donnell, #100088 was amended to include SQ as a route of administration for adenoviral vectors.
- Dr. Campbell, #120159 was amended to include SgK196 as an insert, a kinase-like protein.
- Dr. Dey, #120035 was amended to include additional staff and pET vectors.

The next meeting will be held at 3:30 p.m. on February 14, 2013.

The meeting adjourned at 3:56 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	February 14, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of February 14, 2013
Members Present:	Drs. Adam Clore, Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Haley Sinn and Ms. Carol McGhan
Members Absent:	Drs. Maria Martino-Cardona, Jeffery Meier and Michael Pentella
Guest Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 31, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the minutes of the January 31, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs; however, Dr. Cooper indicated that he had not had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following fifteen rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Smith	[redacted]

- [redacted]
- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Amendt	[redacted]

[redacted]

Dr. Clore joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. Brophy	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Anderson	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Fairley	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Naderi	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Perlman	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Rutkowski	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Cornell	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Dupuy	[redacted]

[redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Moye-Rowley	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Dupuy	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Russo	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Smith	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Johnson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   a) Dr. Sinn had provided the committee with th[redacted] response to the EHS report regarding th[redacted]conducted on December 10, 2012. Dr. Sinn gave a brief overview of the documents and discussed two items of note:
   - The[redacted]biosecurity officer has requested that a summary of maintenance issues be compiled throughout the year by Facilities Management and provided to th[redacted] .
   - There are still questions as to why entry discrepancies occurring in March were not identified during the weekly review initiated in May. Th[redacted]biosecurity officer must ensure that video is recording a three-month time period and complete video/log review each business day.

   Dr. Sinn will send a follow-up letter to the[redacted]regarding the items noted above. No further concerns were raised by the committee. Dr. Duncan made a motion, seconded by Dr. Jones, to approve th[redacted]report and subsequent responses. The members voted unanimously for approval.

4. **New Business**

   a) Three IRB reportable events related to approved rDNARDs were sent to committee members prior to the meeting. Two events involved an unanticipated problem involving risk of side effects to the subjects. Dr. Kirchhoff discussed the adverse events and the relation to the studies conducted at the University of Iowa; subjects are no longer being enrolled or treated under the protocols in question and therefore any risk related to the newly-observed side effects should be minimal. The third event involved mailing a consent form to a subject when the IRB application did not specify that the consent could be mailed. The committee did not have any further concerns with these events.

   b) Dr. Sinn requested that the review of the BSL3 manuals be postponed until mid-April as the manuals are currently under major revisions to meet the new Select Agent Regulations that take effect on April 3rd. The committee agreed to postpone the review until the manuals are finalized with all changes incorporated.

   c) Dr. Sinn informed the committee of a pattern of non-compliance extending over several years involving the housing of mice injected with recombinant HSV-1 in ABSL1 rather than the ABSL2a containment approved by the IBC. This non-compliance was discovered by an IACUC monitor. The history of rDNA approvals was discussed as was the consistent non-compliance with the specified ABSL-2 containment. Several signed documents from Dr. Sluka, the PI, specify ABSL2 housing and therefore no administrative ambiguity has existed during the long period of non-compliance. The PI was advised during a recent meeting with Drs. Sinn, Martino-Cardona and Figler that she must stop all work with recombinant HSV-1 until the committee has duly processed this non-compliance and further reviews proper housing levels for mice involved in these experiments.

Prior to today's IBC meeting, Dr. Walker was informed of the non-compliance and met with Drs. Kirchhoff, Sinn, and White and Ms. McGhan to discuss the issue. After careful review of the history of containment levels used for the HSV-1-injected mice, the group concluded that this constitutes non-compliance that must be reported to NIH/OBA as a violation. The committee discussed the event and the details of both ABSL2a and ABSL2c housing containment. Dr. Cooper made a motion, seconded by Dr. Jarosinski, to report the non-compliance event to NIH/OBA. The members voted unanimously for approval. Drs. Kirchhoff and Sinn will draft a report using the NIH reporting template; the draft report will be sent to committee members prior to the next meeting for final review and approval. Dr. Kirchhoff will inform the PI that this event will be reported to NIH/OBA.

Subsequent to the initial meeting with Dr. Sinn, the PI submitted an amendment request to house HSV-1-injected mice at ABSL1 containment. The request was sent to all committee members prior to the meeting. Dr. Kirchhoff gave a brief overview of how other institutions are housing HSV infected animals and also an overview of the PI's statement that the vector is replication defective due to an interruption of the TK gene.

The committee further discussed the shedding experiments performed by the laboratory and concluded that additional information is required before the amendment can be considered further. Drs. Kirchhoff and Sinn will draft a letter requesting additional information on both the experiments performed to evaluate shedding of the vector and the detailed maps of the recombinant HSV-1 strains Dr. Sluka uses in her experiments.

The next meeting will be held at 3:30 p.m. on February 28, 2013.

The meeting adjourned at 4:37 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
UNIVERSITY
OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: February 28, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 28, 2013

Members Present: Drs. Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Jeffery Meier, Maria Martino-Cardona and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Michael Pentella, and Haley Sinn

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 14, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Meier, to approve the minutes of the February 14, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following five rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Sutterwala	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Sutterwala	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Grueter	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Bonthius	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) The draft report to NIH/OBA detailing Dr. Sluka's non-compliance event was sent to committee members prior to the meeting.

Dr. Kirchhoff discussed the report and asked for comments. Ms. McGhan noted a couple of minor editing changes that she would send Dr. Kirchhoff; Dr. Martino-Cardona noted that changes to the ACURF that were mentioned in the report are not finalized, as the online form is being beta-tested prior to implementation and it could be mid-year before the form is finalized. Dr. Kirchhoff will revise the report to reflect this.

Dr. Jarosinski made a motion, seconded by Dr. Martino-Cardona to send the revised report to NIH/OBA.

Vote: 6 approved, 0 opposed, 0 abstained

b) Additional information requested from Dr. Sluka regarding her amendment request to house HSV-1 infected mice at ABSL1 was sent to committee members prior to the meeting.

Dr. Kirchhoff discussed at length Dr. Sluka's response. Just prior to the meeting, additional information had been sent to Drs. Kirchhoff and Sinn by Dr. Sluka in an email stating that a collaborator had provided information regarding the virulence of the HSV vector and that it was 10,000 times less neurovirulent than the wild type; however, neither the collaborator's name nor any scientific data were provided. Regarding Dr. Sluka's assertion that no leakage or shedding of the virus occurred after the mouse was injected with the rHSV-1, data were not provided to support that claim. After an extensive discussion about the lack of scientific data, it was decided to table this request until more information could be obtained about the projected number of animals that would need to be potentially housed at ABSL2c, and for what period of time they would need to remain in ABSL2c containment before allowing them to move into ABSL1.

Dr. Jones made a motion, seconded by Ms. McGhan, to table this amendment request.

Vote: 6 tabled, 0 opposed, 0 abstained

c) Dr. Kirchhoff discussed the new requirement to register all rDNA work that is exempt under the *NIH Guidelines* and whether or not this should include the cross-breeding of transgenic/knockout rodents that can be maintained at ABSL1 containment. After a brief discussion, the committee agreed that because the issue of cross-breeding of such rodents is not ambiguous and does not present the same concerns as other types of rDNA research, the cross breeding of transgenic/knockout rodents contained at ABSL1 will not require registration with the IBC.

Dr. Meier made a motion, seconded by Dr. Jones, to exempt this work from IBC registration.

Vote: 6 approved, 0 opposed, 0 abstained

4. **New Business**

a) Ms. McGhan reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.

- Dr. Legge, #120319 was amended to include IP and IV as routes of administration.
- Dr. Moore, #110082 was amended to include a research assistant.
- Dr. Salem, #120069 was amended to include a lentiviral vector and GMCSF as an insert.
- Dr. Welsh, #110077, was amended to include siRNA for the inserts listed within his protocol.

- Dr. Henry, #100145, was amended to include Cre-AAV and new staff members.

b) One IRB reportable event related to an approved rDNARD was sent to committee members prior to the meeting. Dr. Lubaroff had submitted this report for an administrative reason, and not one related to an adverse event or patient illness. The committee had no concerns about the reported change to the protocol.

The next meeting will be held at 3:30 p.m. on March 14, 2013.

The meeting adjourned at 4:11 p.m.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	March 14, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of March 14, 2013
Members Present:	Drs. Adam Clore, Keith Jarosinski, Louis Kirchhoff, Jeffery Meier, Maria Martino-Cardona and Haley Sinn and Ms. Carol McGhan
Members Absent:	Drs. Paul Cooper, Leonard Duncan and Bradley Jones
Guest Present:	Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 28, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Meier, to approve the minutes of the February 28, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	G. Lal	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Phillips	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Lin	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Barker	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Campbell	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Campbell	[redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

   a) Dr. Sinn informed the committee that Dr. Sluka has not provided any data to support her statements that there is no shedding of HSV-1 2-4 weeks after the initial injection of the rodents used in her studies. Dr. Sluka will review old files in an attempt to find such data but at this time the committee's request for additional information has not been fulfilled.

   Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to disapprove Dr. Sluka's request for an amendment to lower containment of HSV-1 infected animals from ABSL2a to ABSL1.
   Vote: 7 approved, 0 opposed, 0 abstained

   Dr. Sluka has inquired as to what data the committee would find acceptable to re-review her amendment request to lower containment of her animals to ABSL1. The committee stated that samples should be taken at the surgical site in a short time frame after injection, including 6 hours, 2 and 5 days and then longer time frames of 2 and 4 weeks. PCR testing was also requested by the committee. Drs. Kirchhoff and Sinn will prepare an email to send to Dr. Sluka describing possible experiments that she can perform.

4. **New Business**

   a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
      - Dr. Stapleton, #120021 was amended to an infectious clone of HCV and GBV-C viruses.
      - Dr. Potthoff, #120140 was amended to include a FGF21 co-receptor insert and additional staff.
      - Dr. Wu, #120029 was amended to include DH5α *E.coli* and HEK293 cells as hosts.
      - Dr. Hammond, #120179, was amended to include AAV as a vector, opsin and marker inserts additional routes of administration to animals and additional staff.
      - Dr. Johnson, #110062, was amended to include additional staff.

   b) One IRB reportable event related to an approved rDNARD was sent to committee members prior to the meeting. This report covers similar protocol deviations previously submitted by Dr. Lubaroff;

the report does not involve an event related to the recombinant vector. The committee had no concerns about the reported change to the protocol.

The next meeting will be held at 3:30 p.m. on March 28, 2013.

The meeting adjourned at 4:00 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: March 28, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 28, 2013

Members Present: Drs. Paul Cooper, Leonard Duncan, Bradley Jones, Louis Kirchhoff, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Keith Jarosinski, Maria Martino-Cardona and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:40 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on March 14, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Cooper, to approve the minutes of the March 14, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. Sanford	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	L. McCarter	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	I. Grumbach	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Quelle	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Quelle	[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Colgan	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]t.

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted].

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Fässler	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   There was no old business.

4. **New Business**

   a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
      - Dr. Zabner, #110047 was amended to include a siRNA insert for piezo 1, a membrane protein.

- Dr. Dupuy, #120181 was amended to include a replication defective AAV vector.
- Dr. Smith, #120320 was amended to include several additional inserts from the mouse.
- Dr. Maury, #120060, was amended to include guinea pigs as a host.
- Dr. Comellas, #120002 and 120212, was amended to include an additional staff member.

b) Dr. Sinn discussed an amendment request submitted by Dr. Maury, rDNARD #120057, and forwarded to the committee prior to the meeting. Dr. Maury's request to add guinea pigs to her pseudovirion protocol (#120060) was approved as noted above. She also requested that the containment be reduced from ABSL2a to ABSL1 following VSV pseudovirion administration since the virions are replication defective. The committee agreed with the administration of the pseudovirons and inclusion of additional glycoproteins in the protocol but did not reduce the animal biocontainment level for VSV pseudovirions. Dr. Sinn will contact Dr. Maury's collaborators at Texas Biomedical Research Institute (TBRI) to obtain more information on the replication defective nature of the pseudovirions. An additional concern was raised in that Dr. Maury will ship the immunized animals to TBRI and the committee requested assurance that the animals are not considered infectious following immunization.

The next meeting will be held at 3:30 p.m. on April 11, 2013.

The meeting adjourned at 4:12 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: April 11, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of April 11, 2013

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Paul Cooper, Bradley Jones, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on March 28, 2013**
   No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the March 28, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following five rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	X. Zhu	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Anderson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wilson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Mohapatra	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Lalumiere	[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) Dr. Sinn provided additional information or clarification that was received from the PI regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Sanford, #130039, clarified that he has assumed the role of Facility Director of the Transgenic Animals and Genome Manipulation Facility.
- Dr. McCarter, #130059 provided information regarding the tetracycline resistance gene used in *V. parahaemolyticus*. Dr. Kirchhoff provided an overview of the information; the gene is tetA which is widely distributed in nature and has been shown to be present in a substantial portion of isolates of *V. parahaemolyticus*. Therefore, this insertion is not a major action.

b) Dr. Sinn contacted Dr. Maury's collaborators at Texas Biomedical Research Institute (TBRI) in an effort to obtain more information on the replication defective nature of the VSV pseudovirions. TBRI staff has not worked with this system prior and therefore was unable to provide additional information. Dr. Figler, IACUC Director, contacted colleagues at Pfizer where pseudovirion work has been done and they stated that they would house the animals at ABSL2 out of an abundance of precaution but not because they were worried about shedding.

Dr. Sinn also reported she has contacted USAMRIID and Biosafety staff at Yale but has yet to directly speak with anyone who can provide additional information.

4. **New Business**

a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.

- Dr. McCray, #120062 was amended to include several additional inserts as well as common protein tags.
- Dr. Van Daele, #120263 was amended to include a red fluorescent protein insert.
- Dr. Welsh, #110077 was amended to include stereotaxic injections in to the mouse brain.
- Dr. Giangrande, #120010, was amended to include EphA2 aptamer siRNA chimeras with or without IR dye conjugation.

b) Dr. Sinn informed the committee of a possible reportable event regarding Dr. Maury's housing of VSV pseudovirion infected mice at ABSL1. She will meet with Dr. Maury tomorrow and begin the draft report for NIH/OBA; the report and additional information will be shared with the committee at the next meeting.

c) Dr. Sinn reported that NIH/OBA responded to our last reportable event on Dr. Sluka and no additional actions or information was requested.

d) Dr. Sinn discussed the need to review the BSL3 manuals as stated in the IBC Charter. Ms. McGhan and Dr. Sinn provided information on the recent CDC inspection of our select agent program and stated that the manuals will likely undergo further revision. These revisions will be in addition to those previously made as a result of the regulatory changes in October. The committee requested that the manual review occur after the inspection report is received and all requested changes are incorporated into the manuals.

The next meeting will be held at 3:30 p.m. on April 25, 2013.

The meeting adjourned at 4:02 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

The University of Iowa

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	April 25, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of April 25, 2013
Members Present:	Drs. Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Paul Cooper, Leonard Duncan, and Jeffery Meier
Guest Present:	Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:37 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on April 11, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the April 11, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. O'Donnell	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Klingelhutz	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. McNamara	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Henry	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Strack	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Frank	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) Regarding Dr. Maury's work with recombinant VSV pseudovirions, Dr. Sinn related that she contacted the Biosafety Officer at Yale University to investigate further the replication defective nature of the VSV pseudovirions. Yale researchers do not use pseudovirions but the BSO stated that with Dr. Maury's data we can determine when shedding ceases and with a risk assessment, which is provided under IATA and DOT, we can select the appropriate classification for shipping. Under the regulations in the State of Connecticut, the ability to lower containment levels at Yale is hindered under the human pathogen regulation; once animals are infected with a pathogen, the animals, waste and bedding are considered infectious for the duration of the study, regardless of risk.

Dr. Sinn also stated that she spoke with a veterinarian at the Texas Biomedical Research Institute, where some of Dr. Maury's collaborators work, who in turn spoke with their IBC Chair. The Chair thought that as long as the VSV pseudovirions to which guinea pigs were exposed were replication defective they could be shipped through the usual commercial channels.

Dr. Maury previously stated that she would perform shedding experiments, if requested. The committee requested that Dr. Maury propose experimental methods to examine the animals for shedding; the committee will review the proposal and provide feedback as necessary. After shedding data are reviewed by the committee, an opinion on the proper containment of the VSV pseudovirion work will be rendered.

b) Dr. Kirchhoff discussed the draft report to NIH/OBA regarding Dr. Maury's lack of compliance with the ABSL specified in her rDNARD approved by the IBC that was distributed to committee members prior to the meeting. Minor wording changes were suggested. Dr. Kirchhoff will revise the document as suggested and send the report to NIH/OBA prior to the 30 day deadline.

4. **New Business**

a) Dr. Sinn reported on six amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
   - Dr. Baker, #100134 was amended to include several additional inserts.
   - Dr. Okeoma, #100257 was amended to include an adenoviral-cre recombinase vector.
   - Dr. Zhu, #120331 was amended to include additional plasmids such as pcDNA3.1, pBluescript and the antibiotic resistance gene, zeocin.
   - Dr. Rutkowski, #110203, was amended to include additional inserts related to lipid metabolism and shRNA to silence these genes.
   - Dr. Perlman, #110088 and #120125, were amended to include epitopes and structural proteins from MHV and several open reading frames from MERS-CoV.
   - Dr. Artemyev, #110150, was amended to include an additional staff member.

b) Dr. Sinn discussed an Animal Protocol recently submitted by Dr. Engelhardt covering the infection of CF ferrets with various bacterial species. The bacterial species are not pathogenic in immunocompetent persons. Dr. Engelhardt proposed ABSL2a housing for the CF ferrets involved in these experiments. Mice in similar experiments have been approved at ABSL1. Dr. Sinn asked for input from the committee as to whether ABSL2a containment is necessary, considering the fact that the corresponding ABSL1 mice are housed in closed cages and the CF ferrets will be housed in open cages.

   The committee requested that Dr. Engelhardt indicate if the ABSL2a containment was proposed to reduce the risk of cross contamination of the various bacterial strains among the CF ferrets. If this is the basis for proposing ABSL2a containment, then the CF ferrets can be housed at ABSL2a without further input from the committee. If on the other hand if cross contamination is not the issue, the committee requested that Dr. Engelhardt submit a proposed containment protocol to the IACUC and the IBC for review.

The next meeting will be held at 3:30 p.m. on May 9, 2013.

The meeting adjourned at 4:15 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

The University of Iowa

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: May 9, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of May 9, 2013

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Paul Cooper, Bradley Jones, and Jeffery Meier

Guest Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on April 25, 2013**
   No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the April 25, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Spies	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	E. Sohn	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

Dr. Duncan joined the meeting at this time.

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	M. Spies	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	S. Green	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Polyak	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. Old Business

Committee members received a containment proposal from Dr. Engelhardt's lab, requesting ABSL1 housing for ferrets infected with bacterial strains that are non-pathogenic in the absence of immunosuppression. The committee discussed the bacterial strains and concluded that the strains were a benign group of agents for humans but could cause a health issue for the CF ferrets; however, the ferrets in this study would be susceptible to any agent that a wild-type animal, housed in the same room, might carry. The committee concluded that ABSL1 housing would be appropriate as these bacteria strains are not pathogenic for humans and the researcher is not concerned with the organisms passing among the co-housed ferrets.

Dr. Martino-Cardona made a motion, seconded by Dr. Clore, to approve the request to house ferrets infected with the indicated bacterial strains at ABSL1. The members voted unanimously for approval.

Dr. Sinn will communicate the approval with the IACUC office and inform them that a containment protocol is not necessary. Dr. Sinn will also communicate the approved containment level to Dr. Engelhardt and request that he amend his rDNARD to include *E. coli* strain EC838, as this is a recombinant strain.

4. New Business

Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.

- Dr. Dupuy, #120181 was amended to include several additional inserts expressed in adenovirus, some of which included oncogenes. Dr. Dupuy detailed additional biosafety features that were designed into these adenoviral vectors; including Cre-dependent expression of the oncogene and through sequence design, rendering shRNA non-functional against human p53.
- Dr. Shchelochkov, #120123 was amended to include additional sources of cDNA, morpholinos and an updated staff roster.
- Dr. Polyak, #120098 was amended to include administration of aptamers into mice.
- Dr. Fisher, #120093, was amended to include additional inserts involved in RGS6 signaling and shRNA.

The next meeting will be held at 3:30 p.m. on May 23, 2013.

The meeting adjourned at 3:46 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
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Date:	May 28, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of May 28, 2013
Members Present:	Drs. Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier and Haley Sinn and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Paul Cooper, Leonard Duncan, and Keith Jarosinski
Guest Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 4:05 p.m.

The meeting was closed because it included discussion of proprietary research information and work with select agents.

Business Agenda

1. **Approval of minutes from meetings on May 9, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the May 9, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following five rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Stamnes	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Gillum	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Cassel	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Colgan	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	E. Taylor	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. Old Business

There was no old business.

4. **New Business**

a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
  - Dr. Lee, #120116 was amended to include two shRNA expressing plasmids.
  - Dr. Wright, #120103 was amended to include siRNA inserts.
  - Dr. Engelhardt, #120019 was amended to include a recombinant E.coli to be administered to ferrets.
  - Dr. Perlman, #110079 and #110088, were amended to include an adenoviral vector expressing Dpp4 mouse protease and VEE replicon bearing the coding sequence for the MERS-CoV spike protein, respectively.

b) Dr. Sinn briefly discussed the [redacted] report and the facility response sent to committee members on May 22nd, 2013. Overall, the inspection went well. Issues identified included improper signing of the log book, equipment not maintained properly, and failure to autoclave waste and remove it from the BSL3 laboratory on a daily basis. A factor possibly contributing to the identified deficiencies is the fee structure used by CCOM Administration, under which users are charged for the time they actually spend in the BSL3 laboratory. This may have the effect of causing users to rush to get out of the laboratory at the expense of their completing all tasks required by protocol. The Faculty Director and Assoc. Director of the facility are currently in discussion with CCOM Administration regarding the fee structure.

Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the inspection report; all members voted unanimously for approval.

c) Dr. Sinn reported that NIH/OBA responded to our last reportable event on Dr. Maury and no additional actions or information was requested.

d) Dr. Sinn informed the committee of an incident involving recombinant *Francisella tularensis* that occurred in the BSL3 laboratory on April 10, 2013. The risk assessment for the incident determined that no exposure resulted from the release and thus the incident was reported to CDC simply as a release of a select agent. After reviewing the report, CDC responded that the incident should be viewed as a potential exposure, regardless of PPE worn, and that as such it had to be reported to NIH/OBA. A draft report of the incident written on the NIH/OBA incident reporting template will be sent by Dr. Kirchhoff to committee members for suggestions for revision and approval. He requested that committee members respond to him by E-mail by the close of business on Thursday, May 30th, since he would like to send the report to NIH/OBA on Friday, May 31st.

e) Dr. Sinn informed the committee of an incident involving bedding from mice that had been exposed to wild type and recombinant SARS-CoV that occurred in the BSL3 laboratory on April 18, 2013. As in the case of the incident described above involving *F. tularensis*, risk assessment for this incident determined that no exposure resulted from the release and thus the incident also was reported to CDC as a release of a select agent. In view of CDC's response to the report of the *F. tularensis* incident, however, a draft report of the incident written on the NIH/OBA incident reporting template will be sent by Dr. Kirchhoff to committee members for suggestions for revision and approval. He requested that committee members respond to him by E-mail by the close of business on Thursday, May 30th, since he would like to send this and the report mentioned above to NIH/OBA on Friday, May 31st.

As a result of these incidents and communication with CDC, Drs. Sinn and White will meet with Ms. McGhan to review our procedures regarding spills in the BSL3 laboratory. Based on CDC's interpretation, spills will be treated as potential exposures and the relevant procedures specified in the BSL3 manuals will be modified to be consistent with this interpretation.

f) Ms. McGhan informed the committee of an incident on May 23rd, 2013, involving the BSL3 facility. A leak from the BSL3 shower drain damaged a ceiling light in the BSL2 laboratory below. The leak was due to corrosion at metal connectors of an acid resistant pipe. The corrosion was due to weekly charging the drain with bleach. This resistant pipe was installed a year ago following leaks from the sinks in the BSL3 facility. The sink drains were never restored to their original configuration, but rather the pipes were capped and the sinks currently drain into carboys which are autoclaved out of the facility. The shower is no longer used routinely and serves as an emergency shower only. Both CCOM and FM are working to resolve the issue.

The next meeting will be held at 3:30 p.m. on June 6, 2013.

The meeting adjourned at 4:35 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

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[redacted]

Date: June 6, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 6, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier and Haley Sinn and Ms. Carol McGhan

Members Absent: No one

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on May 28, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Cooper made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the May 28, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following one rDNARD was considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Quelle	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

Dr. Jones joined the meeting at this time.

The second part of the meeting was open to the public.

3. **Old Business**

Dr. Kirchhoff discussed the processing of the reports of the BSL3 incidents involving *Francisella tularensis* and SARS-CoV that were discussed at the last meeting. Final versions of the two reports were sent to committee members shortly after the last meeting for review and approval. In both cases a majority of committee members voted for approval and submission to NIH/OBA., which was done on May 29th.

4. **New Business**

a) Ms. McGhan reported on six amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Welsh, #110077 was amended to include an insert (Cas 9 and mutants).
- Dr. Levasseur, #120170 was amended to include inserting Cre recombinase into an adenoviral vector for use in human and animal cells.
- Dr. Fassler, #130080 was amended to add new hosts (*S. cerevisae*, TOP10, and HB101) and new plasmid vectors and Topo2.1, and a new staff member.
- Dr. Adams, #120119 was amended to add mouse inserts and a plasmid vector.
- Dr. Colgan, #130109 was amended to add plasmid vectors, *S. cerevisae* and inserts.
- Dr. Cheng, #100252 was amended to add staff.

b) Drs. Kirchhoff and Sinn discussed the issue of the appropriate containment level for mice in experiments involving recombinant methicillin-sensitive *Staphylococcus aureus* (MSSA), which currently is ABSL2. It was decided that Dr. Sinn and Ms. McGhan will contact NIH/OBA staff to discuss the possibility of housing mice exposed to MSSA strains at ABSL1. Information obtained from that conversation will be reported at a subsequent IBC meeting.

c) Dr. White described a recent incident in which a Baker SGIII 603TX, which is a class II B2 biological safety cabinet (BSC), located in one of the BSL3 laboratories, was opened to replace the motor but was not decontaminated before the work was started. The Director of the BSL3 laboratory escorted a contractor's technician into the area where the BSC was located. The technician stated that BSCs of the type in question were designed so that they could be opened for such repairs without creating a risk of exposure to potentially contaminated areas, and thus prior decontamination was not required. Nonetheless, when the front access panel was removed to replace the motor, it was immediately evident that the area containing contaminated surfaces had been breached. The technician and the Director were both wearing the appropriate PPE (including scrubs, gown, PAPR, double gloves, dedicated shoes and shoe covers). Exposed surfaces on the inside and outside of the BSC, as well as those in the room were all disinfected as a precaution.

Since relevant personnel are currently unavailable, it is not certain exactly what procedures involving SARS-CoV had been performed in the BSC, but we know that the agent was last used in the BSC on May 11, 2013.

When contacted the following day after the incident, staff of the company that manufactured the BSC agreed to revise their manual for this BSC model to ensure that the information regarding the need for decontamination is accurate. In addition, the company servicing BSCs at the UI will revise its procedures to ensure that all BSCs are decontaminated prior to performing the type of repair described herein.

Dr. White has notified the CDC, NIH/OBA, the Iowa Department of Public Health, and the Johnson County Department of Public Health. The required follow-up reports will be sent to CDC and NIH/OBA in a timely manner and copies will be sent to the other two agencies.

The next meeting will be held at 3:30 p.m. on June 20, 2013.

The meeting adjourned at 4:04 p.m.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

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Date: June 20, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 20, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on June 6, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Clore, to approve the minutes of the June 6, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following five rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Radley	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Sheffield	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Baker	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Talman	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	G. Bishop	[redacted]

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff briefly discussed the draft NIH/OBA report involving the potential exposure to the BSC exhaust HEPA filter which was sent to committee members prior to this meeting. This event was reported to CDC on a Form 3 as a potential exposure, although the potential for exposure was extremely low. The root cause for this incident was the incorrect information in the manual provided by The Baker Company, the manufacturer of the BSC. Staff at The Baker Company stated that the manual for the BSC involved in the incident will be revised and that the company undercontract to service the BSCs at the UI, ENV Services, will make it standard protocol to decontaminate all cabinets on campus prior to the removal of access panels.

Dr. Jones made a motion, seconded by Dr. Duncan, to approve the report and its being sent to NIH/OBA. The members voted unanimously for approval. Dr. Kirchhoff will send an electronic version of the report to all appropriate University staff and NIH/OBA.

4. New Business

a) Ms. McGhan reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.

  - Dr. Milhem, #130008 was amended to change the dosing schedule of the adenovirus-hIL-12 vector administered to patients.
  - Dr. Potthoff, #120140 was amended to include a novel rat insert and additional staff.
  - Dr. Felder, #110012 was amended to add shRNA and a scrambled control expressed from a replication defective lentivirus also expressing GFP.
  - Dr. Campbell, #120159 was amended to include a subunit of the dihdropyridine receptor and additional staff and remove staff.

b) Dr. Sinn reported that NIH/OBA responded to our last reportable event on the spill of medium from a cell culture plate. Apart from the delay in reporting, OBA staff opined that the event was handled appropriately.

c) The next committee meeting will fall on July 4th; Dr. Sinn will send out a Doodle poll to determine the most convenient time to reschedule.

The meeting adjourned at 3:53 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

[redacted]

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Date: July 9, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 9, 2013

Members Present: Drs. Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Jeffery Meier and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Paul Cooper, Maria Martino-Cardona,

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Introduction of new IBC member**
   Dr. Kirchhoff introduced Dr. Lucy DesJardin as a new member of the committee. Dr. DesJardin is currently a program manager at the State Hygienic Laboratory at the University of Iowa.

2. **Approval of minutes from meetings on June 20, 2013**
   No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Jones, to approve the minutes of the June 20, 2013, meeting. The members voted unanimously for approval.

3. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. Dr. Jarosinski reported a conflict of interest with his protocol and will recuse himself from the voting. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Zhan	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	J. Howe	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	D. Soll	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	W. Nauseef	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted].

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	K. Rice	[redacted]

- [redacted].
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Jarosinski	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. Giangrande	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Horswill	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

4. Old Business

a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Radley, rDNARD #130113, specified AAV2 and AAV5 serotypes that will be used in the project.

b) Dr. Sinn reported that NIH/OBA responded to our last two reportable events on the spill of animal bedding and the potential exposure to the BSC exhaust HEPA filter. Apart from the delay in reporting the animal bedding incident, OBA staff opined that the event was handled appropriately.

5. **New Business**

a) Dr. Sinn reported on six amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
   - Dr. Adams, #120119 was amended to include a pcDNA vector and siRNA.
   - Dr. Bishop, #130133 was amended to include additional retroviral vectors, marker inserts, siRNA and micro RNAs and additional staff.
   - Dr. Zhang, #120180 was amended to include additional staff.
   - Dr. London, #120187 was amended to replace the Co-PI and add adenoviral expression of already approved inserts.
   - Dr. Xue, #120173 was amended to include additional transcription factor inserts and demethylase inserts.
   - Dr. Welsh, #110077 was amended to include additional GFP variants and mucin inserts.

b) Dr. Kirchhoff discussed the completed form for a reportable event associated with Dr. Milhem's human gene transfer protocols that had been sent to the committee previously. The event described involved the use over five years of U.S.-sourced bovine serum in the production of the recombinant product administered to study subjects. Since U.S.-sourced bovine serum may be contaminated with the prion that causes bovine spongiform encephalopathy its use might affect the process of obtaining informed consent from study subjects. No concerns or questions regarding the issue were raised by committee members.

c) Dr. Sinn discussed a request from Dr. Campbell to lower the animal housing containment requirements for mice exposed to mouse-adapted influenza (PR8). As the veterinarians were unable to attend this meeting, the committee requested that additional information be provided regarding Dr. Campbell's claims that PR8 cannot infect humans or be transmitted among cage-mate mice following administration. Dr. Sinn will work with both the veterinarians and Dr. Campbell to obtain additional information prior to the next meeting.

The next meeting will be held at 3:30 p.m. on July 18, 2013.

The meeting adjourned at 4:03 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: July 18, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 18, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Paul Cooper, Leonard Duncan, Maria Martino-Cardona, Jeffety Meier

Guest Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on July 9, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the July 9, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Rice	[redacted]

- [redacted]
- [redacted].

[redacted]

- [redacted]
- [redacted].

V[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted] Y. Usachev [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Sivitz	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

Dr. DesJardin joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Engelhardt	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	N. Artemyev	[redacted]

- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. Old Business

a) Dr. Sinn reported that Dr. Campbell's request to house mice infected with a mouse adapted influenza virus, PR8, at ABSL1 has been withdrawn. Dr. Campbell's group will be performing parallel experiments involving a Coxsackie virus in mice that must be housed at ABSL2a and he simply prefers house all the mice in one room.

b) Dr. Sinn reported that NIH/OBA responded to her request for information on proper containment housing for animal experiments. The following containment issues were commented on:

- Dr. Sluka's administration of a replication defective recombinant HSV-1 to mice in muscle or joint tissue. NIH/OBA responded that moving mice from ABSL2 to ABSL1 after shedding has stopped is acceptable. Dr. Sinn will inform Dr. Sluka of NIH/OBA's response and request that if she plans to conduct shedding experiments that a detailed plan of the methodology be reviewed by the IBC prior to initiating the work. Dr. Sinn will also remind her of the obligation to obtain specific approval for such experiments from the IACUC and the IBC through the usual registration forms.

- Dr. Maury's administration of replication defective pseudovirons to immunize mice. NIH/OBA responded that moving mice from ABSL2 to ABSL1 after shedding has stopped is acceptable. Dr. Sinn will inform Dr. Maury of NIH/OBA's response and request that if she plans to conduct shedding experiments that a detailed plan of the methodology be reviewed by the IBC prior to initiating the work. Dr. Sinn will also remind her of the obligation to obtain specific approval for such experiments from the IACUC and the IBC through the usual registration forms.

- Challenging rodents with methicillin-sensitive *Staphylococcus aureus* (MSSA). NIH/OBA responded that housing mice at ABSL1 is acceptable provided that the

OAR staff follow the ABSL1 procedures and housing conditions specified in Dr. Sinn's letter.

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.

- Dr. Morita, #110016 and #110072 were amended to change the location of his laboratory and office as he has now moved to the VA Medical Center.
- Dr. Smith, #110005 was amended to include a new staff member, remove staff and add IV as a route of administration.
- Dr. Felder, #110012 was amended to add human and mouse cell lines for the purpose of generating a replication defective lentiviral vector and testing the efficacy of the vector. An additional room was added for the use of a BSC and training for viral vector production.

The meeting adjourned at 3:50 p.m.

The next meeting will be held at 3:30 p.m. on August 1, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	August 1, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of August 1, 2013
Members Present:	Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, and Haley Sinn and Ms. Carol McGhan
Members Absent:	Drs. Paul Cooper and Bradley Jones
Guest Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on July 18, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Ms. McGhan, to approve the minutes of the July 18, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and had time to review them prior to the meeting. Members were asked to report any conflict with the protocols under review. Dr. Duncan reported a conflict with rDNARD # 130162 and stated that he would recuse himself from the voting. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Niki	[redacted]

[redacted]

[redacted]

- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Irani	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Weiss	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Leslie	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**

   There was no old business.

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
   - Dr. Maury, #120057 and #120060 were amended to remove staff, add new staff and include IM and IP as additional routes of administration.
   - Dr. Nauseef, #130134 was amended to include several additional sources of inserts, a replication defective lentivirus, additional plasmid vectors and several inserts from humans, *Drosophila*, yeast and *E.coli.*
   - Dr. Holstein, # 100333 and #110263 were amended to include additional staff.

b) Dr. Kirchhoff introduced a conflict of interest policy for IBC members that was previously sent to committee members. The committee discussed the circumstances under which a recusal would be appropriate. Dr. Martino-Cardona made a motion, seconded by Dr. Duncan, to approve the policy as an amendment to the IBC Charter. The members voted unanimously for approval.

c) Dr. Sinn discussed an amendment request from Dr. Perlman to rDNARD #120125 that would involve housing MHV-infected mice at ABSL1. The committee questioned Dr. Perlman's statement of his use of wild-type MHV at ABSL1 as the virus is known to be highly contagious. It was unclear if Dr. Perlman is using a variant, such as MHV-1, that is attenuated and is not transmitted to cagemates. The committee requested that additional information be provided such as the specific strain to be used in the proposed experiments and the meaning of "wild type" and "recombinant versions of the lab strain." Dr. Sinn will contact Dr. Perlman and request the additional information.

   By unanimous vote, the committee tabled this amendment request.

d) Dr. Sinn discussed a request from Dr. Gopishetty regarding a proposed project to ferment *Streptococcus oralis* at BSL2-large scale. Dr. Gopishetty was concerned with PPE and handling recommendations for the large scale fermentations. The committee did not have specific concerns with the use of *S. oralis* and asked how Dr. Gopishetty determined that this was a RG2 organism. Dr. Kirchhoff requested that an rDNARD be submitted for consideration. Dr. Sinn will inform Dr. Gopishetty of the discussion.

The meeting adjourned at 4:05 p.m.

The next meeting will be held at 3:30 p.m. on August 15, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	August 15, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of August 15, 2013
Members Present:	Drs. Paul Cooper, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, and Haley Sinn and Ms. Carol McGhan
Members Absent:	Dr. Adam Clore, Leonard Duncan, Lucy DesJardin, Keith Jarosinski, and Bradley Jones
Guest Present:	Drs. James Sheets and Rachel White and Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:39 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 1, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Cooper, to approve the minutes of the August 1, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs and had time to review them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	C-L. Cheng	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Seo	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Stipp	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Thomas	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted] D. Weiss [redacted]

[redacted]

rDNA# PI **rDNA Registration Document Title**

[redacted] R. Piper [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

The committee reviewed additional information provided by Dr. Perlman regarding his amendment request to rDNARD #120125 that would authorize the housing of MHV-infected mice at ABSL1. Dr. Kirchhoff summarized a conversation he had with Dr. Perlman following the initial review of this amendment request and clarified that Dr. Perlman's reference to wild-type MHV was meant to indicate work with a non-recombinant, highly attenuated strain of MHV. Non-recombinant JHM strains of MHV are now listed in the table. The veterinarian members present at the meeting, Drs. Cooper and Martino-Cardona, did not have further concerns with ABSL1 housing for the JHM strains. Dr. Martino-Cardona had done a literature search for the JHM strains and reviewed articles that led her to conclude that ABSL1 is appropriate. The committee requested that Dr. Perlman submit any data he has generated regarding the inability of the JHM strains to be transmitted among cage-mates and to provide articles he or other investigators have published that address the issue of cage-mate transmission. Dr. Sinn will contact Dr. Perlman and inform him of the committee's request.

Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to approve Dr. Perlman's amendment request to house mice injected with the two JHM strains of MHV at ABSL1. The members voted unanimously for approval.

4. **New Business**

a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
   - Dr. Zhan, #120337 was amended to include new staff members.
   - Dr. Tucker, #110005 was amended to include a new staff member, replication AAV as a vector, an insert required for maintenance/function of liposomal pathways in retinal and CNS neurons and several additional retinal transcription factors.

b) Dr. Sinn discussed an amendment request from Dr. McCray to rDNARD #120060 to add RSV (A2 strain) as a new vector. RSV A2 strain is a replication competent virus that has been attenuated for laboratory use. Dr. Kirchhoff explained that he had decided to send this amendment request to the full committee because RSV a major human pathogen that kills more than 10,000 persons annually in the U.S. The committee members focused on the fact that Dr. McCray had not presented any information on the transmissibility and pathogenicity of RSV A2 strain beyond to say that it is attenuated. While they felt that BSL2 containment is likely to be appropriate, they requested references and/or data relating to Dr. McCray's claim that the A2 strain is attenuated. Dr. Sinn will contact Dr. McCray and request such information.

Dr. Cooper made a motion, seconded by Dr. Martino-Cardona, to approve Dr. McCray's request to amendment rDNARD #120060 to include experiments involving RSV A2 strain as a vector for transfecting cells in culture at BSL2, pending the receipt of acceptable information regarding the attenuation of the strain. The members voted unanimously for approval.

The meeting adjourned at 4:09 p.m.

The next meeting will be held at 3:30 p.m. on August 29, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: August 29, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 29, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Bradley Jones, Maria Martino-Cardona, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 15, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Dr. Duncan, to approve the minutes of the August 15, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following three rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Spies	[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Sluka	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Houston	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. Old Business

a. The committee reviewed additional information provided by Dr. Perlman regarding the request for data that addresses the issue of cage-mate transmission of MHV-JHM strains. Dr. Kirchhoff stated that he had searched PubMed and could not find any publications discussing the transmissibility of these strains. The committee had questions on Dr. Perlman's response including the length of time that the cage-mates were asymptomatic and how he determined that they were asymptomatic. Dr. Kirchhoff will contact Dr. Perlman and discuss the committee's concerns.

b. The committee reviewed additional information provided by Dr.McCray regarding the request for data that addresses the attenuation of RSV-A2 strains. Dr. McCray removed the reference to attenuation since this strain of the virus is only known to be less mucogenic in mice. The committee discussed the proposed work and concluded that BSL2 was appropriate for the proposed experiments.

The committee approved the amendment request by a unanimous vote.
Vote: 8 approved, 0 opposed, 0 abstained

4. New Business

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
   - Dr. Jarosinski, #110215 and #130139 were amended to add and remove staff.
   - Dr. Sigmund, #120318 was amended to include protein kinase C-alpha subunit as an insert.
   - Dr. Salem, #120069, was amended to include miRNAs as an insert and new staff.

The meeting adjourned at 4:00 p.m.

The next meeting will be held at 3:30 p.m. on September 12, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: September 12, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 12, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn

Members Absent: Drs. Paul Cooper and Jeffery Meier and Ms. Carol McGhan

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 29, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the minutes of the August 29, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the one pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following rDNARD was considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Schultz	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- By its majority vote, the committee affirmed that the above listed criteria, drawn from the *NIH Guidelines*, have been met.
Vote: 8 approved, 0 opposed, 0 abstained

The second part of the meeting was open to the public.

3. Old Business

The committee reviewed additional information provided by Dr. Perlman in an E-mail message to Dr. Kirchhoff regarding the issue of cage-mate transmission of MHV-JHM strain. Dr. Perlman responded that the unchallenged suckling mice that were cage mates were monitored for symptoms for 10-14 days. Dr. Perlman noted that suckling mice are very sensitive to the virus. The LD50 after intracranial inoculation is less than 1 PFU so that if even 1 PFU entered the brain, the mice would die quickly. Most importantly, this virus does not infect the gut so does not have the properties of the highly-transmissible MHV strains that are the scourges of animal colonies. The committee accepted the response and no further questions were raised.

4. New Business

a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
   - Dr. Leslie, #130165 was amended to add additional inserts and staff.
   - Dr. Carter, #120129 was amended to include another replication defective lentiviral vector and additional inserts.

The meeting adjourned at 3:44 p.m.

The next meeting will be held at 3:30 p.m. on September 26, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: September 26, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 26, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, and Jeffery Meier

Guest Present: Dr. James Sheets

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on September 12, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Clore, to approve the minutes of the September12, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the one pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Ascoli	[redacted]

[redacted]

[redacted]d

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Wemmie	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Mezhir	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Baker	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. Old Business

None

4. New Business

a) Dr. Sinn reported on one amendment to a previously-approved rDNARD that was approved by Dr. Kirchhoff since the last meeting.

- Dr. Baker, #130119 was amended to add cre as an insert in expression vectors such as pRho and pCAG.

b) Dr. Sinn discussed several inquiries she has received recently from researchers involving the registration of exempt rDNA work. These inquiries were responses to the recent publication by EHS of the new policy approved by the IBC under which all recombinant and synthetic DNA must be registered here, even if is exempt under the *NIH Guidelines*. Researchers have asked if research involving only oligonucleotides or restriction fragments must be registered with the IBC. The committee requested that other universities be contacted to understand how they regulate such materials. Dr. Clore explained the procedure followed at Integrated DNA Technologies, the company for which he works, for sequence screening, synthesis, and shipment of oligonucleotides for outside clients. Dr. Sinn will contact colleagues at other institutions and present the information obtained to the committee at the next scheduled meeting.

The meeting adjourned at 3:53 p.m.

The next meeting will be held at 3:30 p.m. on October 10, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	October 10, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of October 10, 2013
Members Present:	Drs. Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Paul Cooper, Lucy DesJardin, Maria Martino-Cardona, and Jeffery Meier
Guest Present:	Mrs. Deborah Kratz, Mr. Tyler Shaffer, and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on September 26, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the September 26, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The sole rDNARD being considered was made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following one rDNARD was considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	E. Abel	[redacted]

- [redacted]s.
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

Dr. Sinn reported on responses she received from other Universities regarding registration of siRNA or DNA restriction fragments. Half the responses required registration with an expedited review of the research, often by the Biosafety Officer and IBC Chair only. The other half did not require registration with the reasoning that the *NIH Guidelines* did not apply to these types of experiments as these molecules do not meet the definition of rDNA, particularly in that they cannot replicate.

The committee discussed the various criteria of synthetic DNA outlined in the *Guidelines*: >100 base pairs, integration, replication, and transcription/translation. Ultimately the committee discussed requiring registration of all synthetic nucleic acid molecules that would be introduced into a biological system, such as an animal or tissue culture cells, regardless of whether it meets the criteria listed above. As members of the IBC will be meeting soon with a group of faculty to discuss the requirement to register exempt rDNA research, announcement of this registration requirement will be postponed until after that meeting in order to allow for further discussion with the researchers.

4. **New Business**

a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff since the last meeting.
   - Dr. Lee, #120341 was amended to add Cav1.4, a calcium channel, as an insert and include mouse as a host in additional rows of the table.
   - Dr. Sigmund, #120061, is approved to use any mouse gene identified in a microarray or high throughput sequencing study and amended the protocol to include any human gene identified in the same manner.
   - Dr. Lee, #120341 was amended to include retinal injection as a route of administration.
   - Dr. McCray, #120062 was amended to include alpha-fetoprotein as an insert.

b) Dr. Kirchhoff discussed an amendment request associated with Dr. Milhem's human gene transfer protocol that had been sent to the committee previously. No changes were made to the study drug or route of administration. No concerns or questions regarding the amendment were raised by committee members.

c) Dr. Sinn discussed the July 201[redacted] and subsequent response from the Faculty and Associate Directors that also had been sent to committee members prior to the meeting. No concerns or questions regarding the report were raised by committee members. Ms. McGhan made a motion, seconded by Dr. Jarosinski, to approve the inspection report and subsequent response. The members voted unanimously for approval.

d) Dr. Sinn notified the committee of a possible exposure of a staff member to a recombinant lentiviral vector. A staff member received a needlstick after she had injected pigs with mouse cells transduced with a replication defective lentiviral vector expressing GFP. Dr. Hartley at UEHC was immediately contacted by the staff member and forwarded information about the incident to Dr. Sinn. Drs. Sinn and White will be meeting with the PI and the staff member tomorrow to investigate the incident further. Furthermore, during initial discussion with the PI, it was determined that IBC approval for use of the lentiviral vector in pigs had not been obtained; the PI is currently working on a new rDNARD and this will be reviewed during the discussion tomorrow. NIH/OBA was notified through email of the potential exposure and the failure to receive IBC approval.

The meeting adjourned at 4:05 p.m.

The next meeting will be held at 3:30 p.m. on October 24, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: October 24, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of October 24, 2013

Members Present: Drs. Maria Martino-Cardona, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Lucy DesJardin, Bradley Jones, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on October 10, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Jarosinski, to approve the minutes of the October 10, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The sole rDNARD being considered was made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following five rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Weiner	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted] C. Ellermeier [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Maury	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Bassuk	[redacted]

[redacted]

The second part of the meeting was open to the public.

3. Old Business

The IBC reviewed a draft report destined for NIH/OBA of the incident involving a potential exposure to a recombinant lentivirus, the PI's failure to receive IBC approval for administration of recombinant cells to pigs, and the PI's failure to list all personnel conducting the experiments involving rDNA.

During the investigation of this incident, it was determined that the assistant who received a puncture from a used cannula was not exposed to a lentivirus, as the cannula contained a control saline solution. However, in addition to using improper procedures for disposing of sharp needles, two issues regarding the rDNARD were found: 1) the approved protocol did not list all personnel working on this project, and 2) although mice were listed as a host, the pigs involved in the experiment were not.

Dr. White explained that she has instructed the PI and staff regarding proper sharps disposal methods. Regarding revising the protocol to include all staff and animal hosts, the current rDNARD expires in October 2013, hence the PI will submit a new rDNARD, and include all the necessary revisions.

A motion to submit the report to NIH/OBA was made by Dr. Sinn and seconded by Dr. Duncan. The motion was approved unanimously.

4. **New Business**

a) Ms. McGhan reported on three amendments to previously-approved rDNARDs that were approved by Dr. Sinn or Dr. Kirchhoff since the last meeting.
   - Dr. Clegg, #120270, was amended to add a new staff member and a graduate student to his protocol.
   - Dr. Jones, #1100126, was amended to add Dr. Lee-Ann Allen as co-PI and also to add 5 of her staff.
   - Dr. Stanford, #130039, was amended to include the use of the GTVC to make the vectors listed in his protocol, as the transgenic core will not be able to make these.

b) Prior to the meeting Dr. Sohn sent to the IBC for review a copy of a revised informed consent form for his approved rDNARD #130094. The committee discussed the revisions and had no concerns. Biosafety staff will add a note in this rDNARD stating that the IBC has reviewed and discussed the revised informed consent document.

c) Dr. Kirchhoff brought a question to the committee for discussion regarding whether co-PIs should be allowed to amend a PI's protocol. Currently only PIs can submit a request for an amendment. Following a brief discussion, it was decided to allow co-PIs to apply for amendments of currently approved rDNARDs. PIs can add laboratory managers or other staff as co-PI, thus allowing these persons to submit requests for amendments. Dr. Duncan made a motion, seconded by Dr. Sinn, to allow this change in the IBC's amendment process.

The meeting adjourned at 3:54 p.m.

The next meeting will be held at 3:30 p.m. on November 7, 2013.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: November 7, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of November 7, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Bradley Jones, Maria Martino-Cardona, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on October 24, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Ms. McGhan, to approve the minutes of the October 24, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following four rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Hansen	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Okeoma	[redacted]

- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Shea	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Tucker	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
There was no old business.

4. **New Business**

a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
   - Dr. Clegg, #120270 was amended to add staff.
   - Dr. Jones, #110126, was amended to add Dr. Lee-Ann Allen as a Co-PI and add Dr. Allen's staff.
   - Dr. Sanford, #130039 was amended to include the Gene Transfer Vector Core for the production of already approved vectors.
   - Dr. Johnson, #110062 was amended to include additional staff and chitosan nanoparticles as a vector.
   - Dr. Lutter, #120120, was amended to add staff.

b) Dr. Sinn discussed the recent announcement in the Federal Register regarding the addition of *P. aeruginosa* as a Risk group 2 bacterial agent and MERS as a Risk group 3 virus to Appendix B of the *NIH Guidelines*. The committee requested that Biosafety staff generate a report that lists which labs currently work with *P. aeruginosa*; Biosafety staff will provide the information to the committee prior to the next meeting for further discussion.

The meeting adjourned at 4:02 p.m.

The next meeting will be held at 3:30 p.m. on November 21, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: November 21, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of November 21, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan and Jeffery Meier

Guest Present: Drs. Nancy Figler, James Walker and Rachel White and Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on November 7, 2013**
   No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Sheets, to approve the minutes of the November 7, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Sheffield	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	O. Shchelochkov	[redacted]

- [redacted]
- [redacted].
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Okeoma	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Fingert	[redacted]

- [redacted].
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Roghair	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted].

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	G. Zode	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Musselman	[redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) Following the announcement that the IBC had voted recently to require PIs to register all rDNA research, including research that is exempt under the *NIH Guidelines*, some PIs expressed concern that this policy change would substantially increase the regulatory burden placed on them by the IBC. Dr. Walker discussed a meeting held by Dr. Dan Reed, VP for Research and Economic Development, basic science departmental heads, and working groups, at which some persons present expressed concern that there was no regulatory basis for the policy change and felt that under the new policy all investigators were being penalized because of the non-compliance with the *NIH Guidelines* by a small number of PIs who had inappropriately claimed that their rDNA research was exempt from registration.

Dr. Walker also discussed a subsequent meeting attended by Drs. Kirchhoff, Sinn, Walker, and White, as well as Mss. Kratz and McGhan, in addition to three basic science faculty members who do rDNA research (Drs. Rory Fisher, Robert Piper, and Scott Moye-Rowley) and who had been assigned to a working group to obtain additional information regarding the new policy by Dr. Reed and the basic science department heads. At that meeting the policy change and the impact of its implementation were explained in detail and questions posed by the three faculty members were answered.

Dr. Walker requested that EHS delay the implementation of the newly-approved policy requiring the registration of all exempt work until additional data can be gathered to determine how many PIs would be affected by the policy. Committee members expressed the opinion that the burden is on the PI to determine whether or not proposed rDNA research is exempt and discussed ways to train PIs regarding the definitions of exempt rDNA research and gather data on the numbers of PIs doing exempt research. EHS staff will work with Drs. Kirchhoff and Walker to develop a process to gather the requested information which will be presented to the committee at a future meeting.

b) Following the recent assignment of RG2 to *Pseudomonas aeruginosa*, a report was sent to committee members prior to the meeting listing the PIs currently working with this organism. The committee discussed proper containment for animal experiments involving *P. aeruginosa* and determined that the University's ABSL1 housing conditions would be sufficient for rodents. However, additional information regarding strain and administration routes was requested for the large animal work (e.g., ferrets, pigs). Biosafety staff will work with the veterinarians to gather the information regarding this issue and present it to the committee at the next meeting.

c) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.
Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:
   - Dr. Tucker, rDNARD #130224, responded that he will test the transduced cells to ensure the absence of Sendai virus prior to inoculating animals, as described in the literature attached to his rDNARD.

4. **New Business**

a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
   - Dr. McCray, #120062, was amended to include four additional inserts, a surfactant protein, an immune regulatory protein, the spike protein from MERS, and a transmembrane protein.
   - Dr. Legge, #120319, was amended to remove staff and add the NP142t-response marker from influenza.
   - Dr. Qi, #120031 was amended to include siRNA.
   - Dr. Rodriguez, #1000272 was amended to include crispr regulatory RNAs originating from *S. pyogenes* and *S. aureus* and the Cas9 nuclease insert.

b) Dr. Figler, IACUC Director, discussed the current practice to approve an Animal Protocol (AP) when the rDNARD is pending approval; this is considered a conditional approval and not allowed by regulators. The IACUC office proposed to educate the PIs that an approved rDNARD is required prior to AP approval or to request that all rDNA work be amended into the AP following rDNARD approval. The IACUC office will work with Biosafety staff to more closely tie the rDNARD approval to the AP approval.

c) Dr. Kirchhoff discussed a recent reportable event associated with Dr. Berg's rDNARD, previously sent to committee members. No concerns were raised by the committee.

The meeting adjourned at 4:36 p.m.

The next meeting will be held at 3:30 p.m. on December 5, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	December 5, 2013
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of December 5, 2013
Members Present:	Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Bradley Jones and Maria Martino-Cardona
Guest Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on November 21, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Ms. McGhan, to approve the minutes of the November 21, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review. Dr. Sinn recused herself from consideration of rDNARD #130231 (Dr. Maury) because a family member is a co-investigator on the project. No other conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Feiss	[redacted]

[redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]t.
[redacted]

Dr. Clore joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Milhem	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Maury	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Hirsch	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Feiss	[redacted]

[redacted]d

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

Review of amendment requests to be considered by full committee:

rDNA#	PI	rDNA Registration Document Title
[redacted]9	J. Engelhardt	[redacted]t [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) Dr. Sinn gave a brief update on the status to require registration of all exempt rDNA research. At this time, PIs completing the routing form associated with grant submission will indicate if the project involves rDNA and if the rDNA research is exempt from the *NIH Guidelines*. Dr. Kirchhoff or Biosafety staff will collect information on the potential level of non-compliance with the *NIH Guidelines* through communication with PIs who do not have a current rDNARD and claim that their proposed rDNA work is exempt. Those PIs with active rDNARDs claiming exemption will not be contacted directly but will receive a memo requesting that they ensure all non-exempt rDNA research is registered with the IBC. The new policy requiring that PIs register all rDNA research, recently-approved by the IBC, will not be implemented, pending acquisition of information relating to the impact of such implementation. After the information is collected it will be provided to the IBC to inform the implementation or revision of the new policy.

b) Dr. Sinn received a response from laboratories administering *P. aeruginosa* to pigs and ferrets. Both labs utilize strain PA01 which may be wild-type or recombinant; the various routes of administration were also discussed. The committee requested that additional information be provided regarding the required changes to housing procedures to move this research from an ABSL1 to ABSL2 containment. Dr. Martino-Cardona, Sheets, and Sinn will meet and draft a containment procedure to be presented to the committee at their earliest convenience.

4. **New Business**

a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
   - Dr. Zhang, #120180, was amended to include pTraffic as a plasmid vector, CD177 and ROR1 inserts, and use of the Transgenic Animal and Genome Manipulation facility to create transgenic mice.
   - Dr. Salem, #120069, was amended to include rat as a host model.

b) Ms. McGhan requested input from committee members on information that should be included in the IBC annual report submitted by Biosafety staff. The committee discussed the possibility of including the pounds of biohazard waste collected annually but felt that an article to the research community addressing proper waste disposal and awareness of the cost of disposing of biohazard waste would be more valuable.

Reporting on previous lab inspections for each PI with an rDNARD under consideration was also discussed. As the lab audit encompasses chemical, radiation and biological review the committee felt that this information would be better addressed by a laboratory safety committee. Any issues directly involving rDNA are brought to the Chair's or committee's attention and this practice should continue. A laboratory utilizing rDNA with persistent issues could be brought to the IBC's attention at the time of rDNARD review; however, a general comment on the status of each lab's previous lab inspection is not necessary.

c) Dr. Sheets requested input on the standard housing conditions for lentivirus vectors as he will be meeting with a faculty recruit. Ms. McGhan stated that common, commercially available lentiviruses utilizing a triple transfection process to generate the replication defective vector are typically housed at ABSL1.

The meeting adjourned at 4:30 p.m.

The next meeting will be held at 3:30 p.m. on December 19, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: December 19, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of December 5, 2013

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Bradley Jones, and Maria Martino-Cardona

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on December 5, 2013**
   No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Dr. Sheets, to approve the minutes of the December 5, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following six rDNARDs were considered:

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	B. Davidson	[redacted]

■ [redacted]r.
■ [redacted]
■ [redacted]
■ [redacted]
■ [redacted]t.
[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	S. Holstein	[redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	C. Grose	[redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	J. Mezhir	[redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	R. Boudreau	[redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	B. Davidson	[redacted]

[redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARD and was judged to be satisfactory:

- Dr. Maury, rDNARD #130231, clarified that the plasmid vectors would not be used in animals; therefore, mice were removed from the host column and the ABSL designation was deleted.

b) Several days before the meeting Dr. Sinn forwarded to committee members Dr. Engelhardt's response to her request for additional information on the EIAV replication defective vector that was the focus of the his request for an amendment to approved rDNARD #120019 sent to EHS on 12/3/2013. The committee discussed whether or not to require Dr. Engelhardt to test for replication competent lentivirus. The members felt that such testing was not necessary. The committee voted to approve the new information, including that related to the use of the EIAV vector as an amendment to rDNARD #120019.
Vote: 8 approved, 0 opposed, 0 abstained

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
   - Dr. Zode, #130199, was amended to include the human myocilin sgRNA as an insert.
   - Dr. Irani, #130158, was amended to include a modified oxidative protein as an insert and adenoviral vectors of already approved inserts.
   - Dr. Barker, #130063, was amended to include Dr. Jerrold Weiss as staff.

b) Several days prior to the meeting Dr. Sinn forwarded to the committee the annual IBC report. The committee discussed the report and had no concerns or comments. Ms. McGhan stated that if there are additional items the committee would like to see in future reports to please inform Biosafety Staff. Dr. Sinn requested that the annual report be submitted in September/October next year to better coincide with the end of the fiscal year. The committee had no concerns with the change in submission date.

Dr. Sheets made a motion, seconded by Dr. Meier, to approve the annual report. The members voted unanimously for approval.

The meeting adjourned at 3:55 p.m.

The next meeting will be held at 3:30 p.m. on January 2, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: January 2, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 2, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Keith Jarosinski, Bradley Jones, Jeffery Meier, and James Sheets

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on December 19, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Dr. Duncan, to approve the minutes of the December 19, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following three rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wold	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted].

[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted] J. Koland [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Ahern	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   None

4. **New Business**

   Dr. Sinn reported on two amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
   - Dr. Tucker, #130224, was amended to include additional staff.
   - Dr. Zavazava, #120008, was amended to include additional routes of administration to mice.

The meeting adjourned at 3:43 p.m.

The next meeting will be held at 3:30 p.m. on January 16, 2014.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	January 16, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	*Minutes of the IBC Meeting of January 16, 2014*
Members Present:	Drs. Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Jeffery Meier, and James Sheets
Guest Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 2, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the minutes of the January 2, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	Z. Ballas	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Slusarski	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Goodheart	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	G. Weiner	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Moye-Rowley	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	L. Wallrath	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Badovinac	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	T. Yahr	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]t.

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
None

4. **New Business**

Dr. Sinn discussed the request to review the containment plan for sorting biohazardous samples submitted by Mr. Justin Fishbaugh, the Technical Director of the Flow Cytometry Facility. Mr. Fishbaugh is applying for a NIH grant and has requested a letter from the IBC stating that the plan adheres to documented biosafety regulations. Mr. Fishbaugh submitted their containment plan which was forwarded to committee members prior to the meeting, along with a draft of an approval letter from Dr. Kirchhoff.

The following items were discussed: (1) the standard referenced on page 52 should read "NSF"; (2) inquire as to whether the facility is still waiting for clarification from FM on the ventilation systems; (3) confirm that a respirator program is in place; and (4) general editing is needed regarding the references to the particular agents (misspellings and such). Biosafety staff will work with Mr. Fishbaugh to address the committee's comments and revise the containment plan, as necessary. There were no further concerns raised by committee members.

Dr. Jones made a motion, seconded by Dr. DesJardin, to approve the containment plan following revision and Dr. Kirchhoff's approval letter. The members voted unanimously for approval.

The meeting adjourned at 4:05 p.m.

The next meeting will be held at 3:30 p.m. on January 30, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: January 30, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 30, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin and Bradley Jones

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:31 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 16, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr.Martino-Cardona, to approve the minutes of the January 16, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. Ferguson	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

Dr. Clore joined the meeting at this time.

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	R. Felder	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

Dr. Meier joined the meeting at this time.

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	J. Engelhardt	[redacted]

- [redacted]
- [redacted].
- [redacted]
- [redacted]
- [redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	J. Martin	[redacted]

[redacted]

- [redacted]e
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	O. Shchelochkov	[redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Badovinac rDNARD #130280, clarified the statement "mouse without any transfer of cells" referred to mice which did not receive a transfer of T-cells prior to agent administration. Dr. Badovinac also clarified that plasmid pPL2 was used to create recombinant *Listeria* carrying the LCMV epitope and chicken ovalbumin.

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
   - Dr. Lin, #120198, was amended to include markers as inserts.
   - Dr. Maury, #120057 and 120060, were amended to include additional cell lines and glycoprotein genes from various viruses.
   - Dr. Stipp, #120045, was amended to include additional cell proliferation inserts.

b) Dr. Sinn reported on the receipt of several trial documents following the continual review of Dr. Russell's human gene transfer rDNARD, #120350. Minor changes were made to the trial, including a Sponsor change, transfer of responsibility for the Interim Medical Monitor Instruction, and the informed consent which involved revising the sponsor and increasing the mobility testing from 45 to 90 minutes. There were no changes that affected the rDNA vector or administration to patients.

   Dr. Kirchhoff also reviewed the trial documents and stated that no changes affected the information reviewed by the IBC. Interested committee members can contact Dr. Sinn for a full copy of the trial documents. No concerns were raised by committee members.

The meeting adjourned at 3:45 p.m.

The next meeting will be held at 3:30 p.m. on February 13, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: February 13, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 13, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin and James Sheets

Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 30, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the January 30, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following nine rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

Dr. Meier joined the meeting at this time.

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	W. Salgado-Pabon	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted].
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	H. Haim	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]et.

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

Proposed revised ABSL2n containment forms for use with ferrets and pigs exposed to recombinant *P. aeruginosa* were developed by Drs. Martino-Cardona, Sheets, and Sinn and sent to the members of the committee for review prior to the meeting. These forms were developed following conversations Drs. Martino-Cardona, Sheets, and Sinn had with staff members in Dr. Engelhardt's and Dr. Zabner's group who foresee working with ferrets and pigs exposed to recombinant *P. aeruginosa*. At today's meeting the question arose as to whether ABSL1 containment level would be appropriate for ferret dams whose pups had been exposed to recombinant *P. aeruginosa* and euthanized some time later. No decision was reached regarding this issue and the members agreed that it should be addressed at a later meeting when specific experimental details are in hand and possibly with input from NIH/OBA.

No additional concerns or comments regarding revised ABSL2n containment forms were made by committee members. Dr. Jones made a motion, seconded by Dr. Meier, to approve the containment forms as submitted. The members voted unanimously for approval.

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
    - Dr. Felder, #140002, was amended to include additional inserts, such as protein kinases and signaling proteins in the inflammatory cytokine pathways.
    - Dr. Engelhardt, #120019, was amended to include a replication defective MMLV vector which will be administered to mice and ferrets.
    - Dr. McCray, #120062, was amended to include PR8 influenza expressing GFP for use in *E.coli* and cell lines only.

b) Dr. Kirchhoff discussed a reportable event associated with Dr. Russell's rDNARD #120350. This event was result of a purely administrative issue and unrelated to the rDNA administered to study subjects. No concerns were raised by the committee.

c) Dr. Kirchhoff discussed at some length the draft of an incident report for NIH/OBA that was sent to committee members prior to the meeting. The report deals with a violation of the *NIH Guidelines* involving experiments with recombinant MERS-CoV in the laboratory of Dr. Stanley Perlman that had not been approved by the IBC. The committee requested clarification regarding which of the experiments involving the MERS-CoV BAC and viral clones had been performed in Dr. Perlman's laboratory under BSL2 containment vs. the BSL3 facility. Considerable discussion was had regarding the latter issue and other elements of the report, during which several revisions were suggested. The possible implementation of monitoring and corrective actions to prevent the recurrence of violations of this type were also discussed at length. Dr. Kirchhoff will make the suggested changes in the report and send the revised version to the committee for further review. The committee agreed to hold a special meeting to discuss the revisions and subsequent submission of the report to NIH/OBA.

The meeting adjourned at 4:42 p.m.

A special meeting will be held at 3:30 pm on February 17, 2014

The next regularly scheduled meeting will be held at 3:30 p.m. on February 27, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: February 17, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 17, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 13, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the February 13, 2014, meeting. The members voted unanimously for approval.

2. **Old Business**
   a) Dr. Kirchhoff discussed two amendments to previously-approved rDNARDs, submitted by Dr. Stanley Perlman and sent to committee members prior to the meeting.
      - rDNARD, #120125, has been amended to include additional MHV inserts and two additional staff members. All required training has been completed by the new staff. The committee requested clarification on the difference between MHV wild type strain and MHV-A59 strain, the latter of which is included in the new information. Biosafety staff will contact Dr. Perlman and revise the document as appropriate.
      - rDNARD, #110079, was amended to include the N-protein from MERS-CoV.

      Dr. Duncan made a motion, seconded by Dr. Jones, to approve the amendment requests; however, approval of #110079 is contingent upon obtaining a satisfactory response from the PI regarding the information requested by EHS's Biosafety staff. The members voted unanimously for approval.

   b) Dr. Kirchhoff discussed the revised draft of the rMERS-CoV incident report that was sent to committee members prior to the meeting. Minor edit requests were requested by members but no concerns were raised with the revisions. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the circulated version of the report and submit it to NIH/OBA. The members voted unanimously for approval.

The meeting adjourned at 3:47 p.m.

The next meeting will be held at 3:30 p.m. on February 27, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
UNIVERSITY
OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: February 27, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: *Minutes of the IBC Meeting of February 27, 2014*

Members Present: Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Keith Jarosinski, and Jeffery Meier

Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 17, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the February 17, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following four rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Salgado-Pabon	[redacted]

- [redacted]
- [redacted].

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	D. Berg	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	F. Miller	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	L. McCarter	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Perlman rDNARD #120125, stated that MHV-A59 is a strain of MHV that is 95% similar to the JHM strains at the nucleotide level. It is both hepatotropic and neurotropic, whereas the JHM strains are just neurotropic. It also tends to grow to higher titers in cell culture than does the JHM strain, thus making it highly useful to study MHV in cell culture.
- Dr. Haim rDNARD #140022, stated that he was previously a post-doc at Harvard and while there was unaware of the *NIH Guidelines,* since the PI handled all such administrative issues. Prior to submitting the rDNARD he was carrying out the research described in the protocol. He did not receive any information regarding the *NIH Guidelines* and associated registration requirements at the University of Iowa and submitted the protocol as soon as he was informed of the requirements. Following further investigation, it was determined that Dr. Haim was not listed on the new hire list provided by the Provost's office; the reason for his not being on the list is under review by EHS staff.

4. **New Business**

a) Dr. Sinn reported on six amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
   - Dr. Engelhardt, #140005 and #120019, were amended to include the jugular vein as an additional route of administration in ferrets.
   - Dr. Habelhah, #110232, was amended to include an additional cell line and the replication defective MMLV vector, pQCXIH.
   - Dr. Legge, #110319, was amended to include an additional staff member and incorporate rDNARD #110204; there were no changes necessary in the insert/host/vector table.
   - Dr. Henry, #130093, was amended to include additional staff, remove staff, and add transcription factor inserts and an additional replication defective lentiviral vector.
   - Dr. Goel, #110121, was amended to add and remove staff.

b) Dr. Sinn discussed the December 2013 inspection of the [redacted] and the [redacted]'s subsequent response, which was previously sent to committee members. There were no major concerns identified during the audit and the response was deemed acceptable. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the inspection report and subsequent response. The members voted unanimously for approval.

c) Dr. Kirchhoff discussed a reportable event associated with Dr. Russell's rDNARD #120350, a copy of which was sent to committee members prior to this meeting. This event was unlikely related to the rDNA vector administered. No concerns were raised by the committee.

d) Drs. Martino-Cardona, Sheets, and Sinn modified waste handling procedures for ABSL1 small animal housing involving recombinant agents. The revised procedures were sent to committee members prior to the meeting. The committee determined that the waste should be disposed of as biohazardous for the life of the animals exposed to rDNA and therefore the revised procedure will so indicate. The most effective ways to communicate this change to the research community were discussed. EHS's LabNews and annual audits will be utilized in addition to providing the information during Animal Protocol and amendment approvals involving ABSL1 recombinant agents. Possible use of the Animal Resource's listserv will also be reviewed.

e) Dr. Maury submitted a protocol for testing for shedding following VSV-pseudovirion administration with the intent to reduce the containment of mice from ABSL-2 to ABSL-1 housing, as previously approved by NIH/OBA. The protocol was sent to committee members prior to the meeting. The committee requested further information on the sensitivity of the assay and why the animals must be euthanized for the sample collection when nasal instillation is the route of administration. Dr. Sinn will contact Dr. Maury and report the additional information at the next IBC meeting.

f) Dr. Sinn discussed the need for the IBC to review the BSL3 manuals for the [redacted] and the [redacted]. The manuals have undergone significant review and revision as a result of the April 2013 CDC inspection and 2014 registration renewal. The manuals are now in the final form although a response from the CDC inspection is still outstanding. A hard copy of the manuals will be available for review from 2:30-3:30pm in room [redacted] 1189 on March 13, just prior to the next IBC meeting. Please contact Haley to arrange an alternative time to review the manuals if conflicts arise. The room is reserved through 4:30 pm and starting at 3:30 pm the meeting will be held here.

The meeting adjourned at 4:30 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on March 13, 2014 in room MERF 1189.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	March 13, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of March 13, 2014
Members Present:	Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Keith Jarosinski, Jeffery Meier, and James Sheets,
Guests Present:	Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 1189 MERF, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 27, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the February 27, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Hohl	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	K. Parekh	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	N. Harata	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	L. Zingman	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	A. Lidral	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Ahern	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Cullen	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Morita	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Morita	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**

   Dr. Kirchhoff informed the committee of NIH/OBA's response to the incident report involving the unapproved generation of recombinant MERS-CoV in Dr. Stanley Perlman's laboratory. Dr. Kirchhoff and Biosafety staff will review the monitoring program that was instituted several years ago for another laboratory that had violated the *NIH Guidelines* and will design a program for monitoring rDNA work in Dr. Perlman's laboratory. Information will be brought back to the committee at the next meeting for discussion and subsequent implementation.

4. **New Business**

   a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
      - Dr. Leslie, #130165, was amended to include additional lentiviral vectors and inserts, including markers, a kinase, repair gene and oncogenes.
      - Dr. Wilson, #130083, was amended to add additional staff.

   b) Dr. Kirchhoff discussed an amendment request from Dr. Haim, previously sent to the committee for review. There were no concerns raised by the amendment request and the committee voted unanimously for approval.

   c) Dr. Sinn provided copies of the [redacted] and [redacted] manuals to the committee members prior to the meeting. The committee provided minor comments regarding revisions which will be distributed to the appropriate program administration. Dr. DesJardin made a motion, seconded by Dr. Martino-Cardona, to approve the [redacted] manuals. The members voted unanimously for approval.

The meeting adjourned at 4:15 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on March 27, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: April 10, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of April 10, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Bradley Jones, Maria Martino-Cardona, and Jeffery Meier

Guests Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on March 27, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Ms. McGhan, to approve the minutes of the March 27, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	E. Abel	[redacted]

- [redacted].

[redacted]

- [redacted]

[redacted]

- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Davidson	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	N. Harata	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Houtman	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted].

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Martin	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

   a) Prior to today's meeting Dr. Maury sent to EHS staff and the committee a PowerPoint presentation depicting her work involving the vaccination of mice with VSV-pseudovirions and the Ebola virus glycoprotein gene. Dr. Maury attended today's meeting via phone and reviewed the content of her slides in detail with the committee members, after which they asked several questions. They requested that she try to increase the sensitivity of the detection assay and also raised issues relating to the handling of the mice after vaccination, IACUC approvals, and USDA permits. Dr. Maury stated that she will request an amendment to her USDA permit that will cover shipment of the vaccinated mice.

   Dr. Maury agreed to attend the next IBC meeting and present at that time data relating to post-vaccination shedding of VSV pseudovirions and the sensitivity of her assay.

4. **New Business**

   a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
      - Dr. Chen, #110103, was amended to update the laboratory personnel, include the generation of a transgenic mouse, update the antibiotic resistance genes and update the Animal Protocol number.
      - Dr. Sluka, #130160, was amended to add additional staff.

   b) Dr. Kirchhoff discussed his revisions of the informed consent form that is part of Dr. Russell's rDNARD, #120350, which previously was sent to the committee for review. In his view the revisions were not related to the rDNA administered to the study subjects but rather involved the mechanics of administration. The consent document was expanded to include language addressing a lifting of the retina after rDNA injection. Dr. Kirchhoff provided an edited version of the document which Dr. Sinn will send to the IRB. No further concerns were raised by the members of the committee.

c) Dr. Sinn discussed changing the date of the next IBC meeting due to a conflict with the CDC Select Agent inspection. A doodle poll will be sent around to determine member availability on alternative dates for the meeting.

The meeting adjourned at 4:30 p.m.

The next regularly scheduled meeting will be determined.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
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OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: April 28, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of April 28, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Louis Kirchhoff, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Keith Jarosinski, Bradley Jones, and Maria Martino-Cardona,

Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on April 10, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Sheets, to approve the minutes of the April 10, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with 3 rDNARDs and will abstain during the votes. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	Z. Ballas	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Scheel	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Scheel	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Perlman	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted]	P. Sinn	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**

Prior to today's meeting Dr. Maury sent to EHS staff a three-slide PowerPoint presentation containing shedding data from her work involving the vaccination of mice with VSV-pseudovirions and the Machupo virus glycoprotein gene. The committee discussed the signal found in the *in vivo* samples and requested that Dr. Maury clearly and explicitly state her experimental methods, results and interpretation of those results. Dr. Sinn will contact Dr. Maury and request the additional information.

Dr. Sheets discussed Dr. Maury's USDA permit and asked if the IBC will need to review any updates made to this permit to cover the shipment of these mice. Ms. McGhan stated that it is sufficient for the Office of Animal Resources to ensure that the proper permit is in place.

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
   - Dr. Taylor, #130110, was amended to include additional inserts involved in targeted cutting of DNA and add staff.
   - Dr. McCray, #120062, was amended to add the glycoprotein from Junin virus as an insert.

- Dr. Engelhardt, #140005, was amended to include recombinant E. coli (EC838) which will be administered to ferrets and additional routes of administration.

b) Dr. Sinn discussed a revised procedure to register the Gene Transfer Vector Core's broad approval rDNARDs. The committee agreed to the revised procedure; Dr. Sinn will work with Ms. Scheel to submit the broad approval request and subsequent quarterly reports in a manner that is consistent with the revised procedure..

The meeting adjourned at 4:48 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on May 8, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
UNIVERSITY
OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: May 8, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of May 8, 2014

Members Present: Drs. Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Lucy DesJardin, and Jeffery Meier

Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on April 28, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Sheets, to approve the minutes of the April 28, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with 3 rDNARDs and will abstain during the votes. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following fourteen rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Zabner	[redacted]

- [redacted]
- [redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Spitz	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Scheel	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Sah	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Sheffield	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. Sinn	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Maury	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Lira	[redacted]

[redacted]

- [redacted]
- [redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Segaloff	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Engelhardt	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]t.

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Comellas	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	T. Tootle	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
Dr. Kirchhoff provided revised language to replace the BSL2* footnote in the table attached to Dr. Perlman's pending rDNARD, #140083 prior to today's meeting. The committee discussed the language and had no concerns. Dr. Sinn will contact Dr. Perlman to discuss the revision and update the rDNARD as necessary.

4. **New Business**

a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
- Dr. Taylor, #130110, was amended to include retro-orbital sinus as a route of administration.
- Dr. Harty, #120163, was amended to include MHV-JHM and a replication defective lentivirus as vectors and shRNA against apoptosis regulating genes, VSVG and gag/pol as inserts.

b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Wu's amendment request to rDNARD #120029. The committee discussed the use of the replication defective rabies virus and determined that ABSL2a was the appropriate containment. However, the source and function columns are incorrect. Mrs. Kratz stated that additional inserts need to be added in order to cover the work entered in the AP as an amendment. Biosafety staff will work with Dr. Wu to ensure the table is complete and accurate. The committee unanimously approved the amendment request pending the addition of this information.

The meeting adjourned at 4:24 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on May 22, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
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Environmental Health & Safety
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Ph. 319-335-8501
Fax 319-335-7564

Date: May 22, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of May 22, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Dr. Jeffery Meier

Guests Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on May 8, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Sheets, to approve the minutes of the May 8, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with 1 rDNARD and will abstain during the vote. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following four rDNARDs were considered:

rDNA#.	PI	rDNA Registration Document Title
[redacted]	M. Singh	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. McGowan	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Scheel	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Gordon	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   None

4. **New Business**

a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
   - Dr. Welsh, #110077, was amended to include several inserts, additional staff and the intracranial route of administration.
   - Dr. Okeoma, #130218, was amended to include mutations of already approved inserts, the Cas9 nuclease from *S. pyogenes* and an additional plasmid vector.
   - Dr. McCray, #120062, was amended to remove Iowa State University as a collaborating institution with PIV5 research in pigs; no pig work with PIV5 will be performed at the University of Iowa and therefore pig has been removed as a host from the table. Any animal work with this plasmid will have to be approved by the appropriate committees at the collaborating site.

b) Dr. Sinn reported that she, Dr. Jarosinski, and Mrs. Kratz met with Dr. Perlman and his staff members involved in rDNA research as part of the monitoring program imposed as a result of the laboratory's violation outlined in the recent report to NIH/OBA. At that meeting ongoing rDNA research was reviewed and it was determined that human cell lines must be added as a host to both approved rDNARDs (#s 120125 and 140083) In addition, Perlman staff member J. Athmer needed to be added to rDNARD #140083 by amendment and this was done subsequently by Dr. Perlman and approved by Dr. Kirchhoff. The next monitoring meeting will take place in August.

c) Prior to today's meeting, Dr. Sinn forwarded a document describing a reportable event associated with Dr. Lubaroff's rDNARD #120345. Dr. Kirchhoff discussed the event and no additional concerns were raised by the committee.

d) Prior to today's meeting, Drs. Martino-Cardona and Sheets provided proposed language to add to the rDNARD approval letters regarding animal work approved in the rDNARD but not the Animal Protocol (AP). IACUC staff are currently contacting PIs with non-congruent approvals and informing them of the need to amend their AP; however, as some animal experiments may be planned for the distant future, PIs are requesting to amend the AP at a later date. IACUC administers must inform Biosafety Staff that the language is to be added into the approval letter; otherwise, the language will not be included.

   The following language will be included when appropriate: "Please be aware that your approved rDNA Registration Document (rDNARD) lists the use of additional species or procedures that are not listed/approved in the associated Animal Protocol/s. Only procedures approved by the Institutional Animal Care and Use Committee (IACUC) may be conducted under this approved rDNARD. You must amend your Animal Protocol and receive IACUC approval prior to conducting any currently unapproved procedures or utilizing a currently unapproved species."

e) Mrs. Kratz discussed the review of the rDNARDs by the committee and requested feedback prior to the meeting in order to expedite processing of the rDNARD following the meeting. The AP approvals are now withheld until all rDNA work has been approved and PIs are frustrated at the delay in approvals. Dr. Martino-Cardona stated that previous reviews of APs involved frequent communication with the PIs who then became frustrated at the multiple emails/phone calls from the IACUC. The committee decided that our current process of collecting concerns/questions at the time of the meeting is appropriate and will result in minimal interruptions to the PI. The average time for AP approval is 4-6 weeks and PIs should have no issues receiving rDNA approval within the time frame of the AP review if the rDNARD is submitted simultaneously with the AP.

The meeting adjourned at 4:19 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on June 5, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	June 5, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of June 5, 2014
Members Present:	Drs. Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Lucy DesJardin, and Jeffery Meier
Guests Present:	Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on May 22, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the May 22, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following three rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Kirby	[redacted]

- [redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Scheel	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Goel	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**

Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Maury's shedding data on VSV-pseudovirions. The committee discussed the limit of detection and felt that Dr. Maury's experimental design is reasonable and that the initial data support changing the containment level of the vaccinated mice to ABSL1. The committee requested that the background level be added to slide 6 of the document.

As stated in the information submitted by Dr. Maury, the Machupo Virus glycoprotein experiment will be repeated and samples will also be collected at 24 and 72 hours after vaccination for the Ebola virus glycoprotein studies. Dr. Sinn will relay the committee's request to report the background level and also suggest that Dr. Maury submit an amendment request to lower the containment of the VSV-pseudovirion mice to ABSL1 when the additional data is submitted to the committee for review.

4. **New Business**

a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
    - Dr. Abel, #140069, was amended to include lentiviral expression of several shRNA inserts against hormone receptors, mitochondrial fusion, prosurvival, and chaperon proteins.
    - Dr. Henry, #130093, was amended to include AAV as vector for an already approved insert.
    - Dr. Leslie, #130165, was amended to include lentiviral expression of shRNA against an estrogen receptor.
    - Dr. Chapleau, #140068, was amended to include AAV as a vector for an already approved insert and adenoviral expression of shRNA against a swell-activated chloride channel.
    - Dr. Abboud, #110051, was amended to include adenoviral expression of shRNA against a swell-activated chloride channel

b) Prior to today's meeting, Dr. Sinn forwarded to committee members Ms. Scheel's request to amend rDNARD #140118 which lists in a table inserts that fall outside the GVTC's broad approval. The committee requested that a footnote be added to the vector column of the table that refers the reader back to the replication-defective description of all the vectors listed in the approved rDNARD. The committee also discussed how to handle future amendment requests from the GVTC and decided that the process currently being utilized is appropriate. In this process, Dr. Kirchhoff reviews the substance of each amendment request and either approves the request or sends it to the committee for full review.

Ms. McGhan made a motion, seconded by Dr. Sheets, to approve the amendment request. The members voted unanimously for approval.

The meeting adjourned at 4:00 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on June 19, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

[redacted]

Date: June 19, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 19, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan, Bradley Jones, and Jeffery Meier

Guests Present: Mrs. Deborah Kratz and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Dr. Kirchhoff began the meeting by thanking Mrs. Kratz for her dedication and commitment to her job as she prepares for her retirement on June 30. Additional members also expressed their gratitude for her service. Dr. Sinn introduced Dr. Maes, our new Associate Biosafety Officer who will be involved in the rDNA program. Dr. Maes gave a brief overview of her academic career and interests.

Business Agenda

1. **Approval of minutes from meetings on June 5, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Dr. Sheets, to approve the minutes of the June 5, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following four rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Welsh	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Sah	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Kuehn	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Burnett	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
None

4. **New Business**

a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.
    - Dr. Weiss, #130173, was amended to include an insert involved in cellulose binding, a pET vector and additional staff.
    - Dr. Banfi, #120191, was amended to include microRNA inserts and a gene involved in transcriptional regulation and the pBS vector.
    - Dr. Janz, #130015 and 130019, were amended to include additional staff.
    - Dr. Engelhardt, #130148, was amended to include injection of ASPM1 mRNA (mitotic spindle function) into a ferret embryo and additional routes of administration for ferrets.
    - Dr. Rutkowski, #110203, was amended to include additional genes related to peripheral metabolism and ER stress in an AAV vector.

b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Berg's annual report to OBA, associated with rDNARD #140031. Dr. Kirchhoff briefly discussed the report, noting that no SAEs were related to the rDNA administered and that the project is closed to new enrollment at the University of Iowa. There were no concerns regarding the report were raised by the committee members.

c) Dr. Sinn will send an email to all committee members to determine their availability for the next regularly scheduled meeting on July 3 and based on the responses will determine if the meeting should be rescheduled.

The meeting adjourned at 3:54 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on July 3rd.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: July 3, 2014

To: *Members of the Institutional Biosafety Committee (IBC; rDNA Committee)*

Subject: Minutes of the IBC Meeting of July 3, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, James Sheets and Ms. Carol McGhan

Members Absent: Drs. Bradley Jones and Haley Sinn

Guests Present: Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on June 19, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. DesJardin made a motion, seconded by Dr. Clore, to approve the minutes of the June 19, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following three rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Comellas	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]

- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. McCray	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Chen	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   None

4. **New Business**

   a) Ms. McGhan reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.
   - Dr. Jarosinski, #130139, was amended to include additional hosts, vectors and animals, e.g., full Marek's disease virus genome, modified endogenous vial telomerase RNA, MDV UL44 glycoprotein C, an ILTV (infectious laryngotracheitis virus) glycoprotein and a turkey herpesvirus glycoprotein.
   - Dr. Anderson, #130079, was amended to add a new staff member in the lab, and additional strains of non-pathogenic *E coli.*

- Dr. Lal, #130037, was amended to add an insert (shRNA to ECM1) and pLKO.1 vector (Lentivirus), another cell line, SCID or NOG mice and a new route of infection.
- Ms. Scheel, #140118, added a mouse insert for use with an AAV vector and hosts consisting of E coli, Sf9 and HT 1080 cells.

The meeting adjourned at 3:45 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on July 17th.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: July 17, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 17, 2014

Members Present: Drs. Lucy DesJardin, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Leonard Duncan, Jeffery Meier, and James Sheets

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on July 3, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the July 3, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Sutterwala	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	Y. Vyas	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	C. Thomas	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	R. Smith	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	A. Horswill	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Moore	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	H. Habelhah	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wilson	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	L. Norian	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. DeMali	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**

   a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

   Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

   - Dr. McCray rDNARD #140143, stated that SARS-CoV is in the title because it is the title of the associated grant. The strain of MERS-CoV is wild-type MERS-CoV.

   b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Maury's most recent results regarding post-vaccination shedding by mice vaccinated with VSV pseudovirions bearing the glycoproteins of Ebola and Marburg viruses. Dr. Kirchhoff discussed the results and asked the committee members if they had concerns with the experiments performed or the results. There were no concerns raised and members felt the data reasonably demonstrated that there was no shedding following the vaccinations. Dr. Maury also submitted a request to lower the containment level for the VSV pseudovirion vaccinated mice from ABSL2 to ABL1 as an amendment to rDNARD #140095.

   The committee voted unanimously to approve Dr. Maury's amendment request.

4. **New Business**

   a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.

   - Dr. Parekh, #130267, was amended to include additional staff.
   - Dr. Perlman, #120125, was amended to include additional routes of administration to animals.

The meeting adjourned at 3:50 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on July 31st.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: July 31, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 31, 2014

Members Present: Drs. Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Lucy DesJardin, Bradley Jones, Jeffery Meier, and James Sheets

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on July 17, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the July 17, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	O. Shchelochkov	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title

[redacted]	L. Zingman	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	C. Zhao	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	D. Lubaroff	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	C. Benson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	B. Boles	[redacted]

- [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	N. Karankikar	[redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Price	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   There was no old business.

4. **New Business**

   a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.
      - Dr. Salem, #120069, was amended to include additional inserts, a cmRNA vector and administration to animals via implantation in calvarial defects.
      - Dr. Salgado-Pabon, #140017, was amended to include subcutaneous as an additional routes of administration to animals.
      - Dr. Welsh, #140122, was amended to include the FOXJ1 promoter as an insert.
      - Ms. Scheel, #140118, was amended to include lactate dehydrogenase A as an insert.
      - Dr. Vyas, #140129, was amended to include an additional replication-defective lentiviral vector and microRNA for HMGN1, a nucleosomal binding protein, as an insert.

   b) Prior to today's meeting, Dr. Sinn forwarded to committee members the Gene Transfer Vector *Core's second quarter report for 2014.* There were no concerns raised by the committee. Dr. Duncan made a motion, seconded by Ms. McGhan, to approve the report; the members voted unanimously for approval. Dr. Sinn will attach this report to the GTVC's broad approval rDNARD, #140118.

The meeting adjourned at 3:50 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on August 14th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
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OF IOWA

Environmental Health & Safety
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Date: August 14, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 14, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Bradley Jones and Jeffery Meier

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on July 31, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Dr. Desjardin, to approve the minutes of the July 31, 2014, meeting. The members voted unanimously for approval.

2. ***rDNARDs under review:***
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; *Dr. Jarosinski reported a conflict with rDNARD #140175 (P. Schlievert)* and will abstain on that vote. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following nine rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Hunter	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. Schlievert	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	F. Abboud	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Sieren	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Tanas	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	W. Paradee	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wilson	[redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   There was no old business.

4. **New Business**

   a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
      - Dr. Banfi, #120191, was amended to include microRNA inserts and a replication defective AAV vector.
      - Dr. Harty, #110264, was amended to include RSV attachment and membrane proteins as inserts and a replication defective adenoviral vector.

- Dr. Perlman, #140083, was amended to include additional plasmid constructs.

b) Prior to today's meeting, Dr. Sinn forwarded to committee members a reportable event associated with Dr. Russell's rDNARD, #120350. The study protocol required reporting any hospitalization as a severe adverse event even though the investigators indicated that the event was definitely not related to the study drug. The committee members had no concerns with the report.

The meeting adjourned at 3:50 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on August 28th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: August 28, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 28, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Jeffery Meier

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 14, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the August 14, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Klesney-Tait	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M.S. O'Dorisio	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Mullins	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	X. Meng	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	D. Rutkowski	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Mahajan	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Manak	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Mullins	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Klingelhutz	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Klingelhutz	[redacted]

- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
There was no old business.

4. **New Business**

a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
   - Dr. Spies, #120082, was amended to include the High Throughput Screening Facility, new staff and a new funding source.
   - Dr. Tucker, #130224, was amended to include a transgenic Pro23His rhodopsin pig.
   - Dr. Weiss, #130173, was amended to include additional plasmid vectors and a Keio collection of E. coli K-12 knockout mutants.
   - Dr. Chapleau, #130173, was amended to include an additional shRNA-AT1Ra insert.

b) Dr. Sinn reported that she, Dr. Jarosinski, and Mrs. Dockstader met with Dr. Perlman and his staff members involved in rDNA research as part of the monitoring program imposed by the committee as a result of the laboratory's violation outlined in the recent report to NIH/OBA. At that meeting ongoing rDNA research was reviewed and it was determined that plasmid vectors must be added for cloning of the MHV nsp3 and nsp15 inserts by amendment. This was done subsequently by Dr. Perlman and approved by Dr. Kirchhoff as an amendment to approved rDNARD #120125.

   In addition, Dr. Perlman added an MHV-JHM vector carrying Cre-recombinase to rDNARD #120125 and a Bac clone and infectious MERS-CoV vector carrying a mutated S protein of MERS-CoV to rDNARD #140083.

   The next monitoring meeting with Dr. Perlman and his staff will take place in November.

c) Prior to today's meeting, Dr. Sinn informed committee members regarding Dr. Maury's request to the IACUC to remove mice infected with recombinant infectious VSV from the ABSL2a housing for imaging purposes. Prior to this meeting Dr. Sinn forwarded to all committee members Dr. Maury's relevant rDNARD and a protocol previously developed by OAR for removing mice infected with recombinant replication deficient VSV. After considerable discussion, the committee decided to request additional information and clarification from USDA regarding this issue. The latter approach was taken because Dr. Maury's USDA permit does not contain restrictions on where the work involving mice exposed to recombinant infectious VSV may be carried out, but a prior USDA permit for Dr. Goel did restrict the work with similar mice to her laboratory and the ABSL2a room. Dr. Sinn will contact the USDA for clarification and inform Dr. Maury of the committee's decision.

d) Ms. McGhan discussed the Biosafety Stand-down and National Biosafety Stewardship Month (September 2014) established by OSTP and NIH. In the early 2000s, and again some years later when the Select Agent Program was established at UI, EHS asked all PIs to review their freezer inventories of biological materials. In addition, laboratories currently are required by EHS to provide a copy of their biological agent inventories at the time of the annual laboratory review. These inventories are required to include agents actively being used as well as those in storage.

Consistent with the goals of the Biosafety Stand-down and National Biosafety Stewardship Month Ms. McGhan and Drs. Sinn and Walker will meet to review the biosafety programs currently in place and determine what, if any, efforts need be made to strengthen the oversight at the University.

The meeting adjourned at 4:10 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on September 11th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
UNIVERSITY
OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	September 11, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	*Minutes of the IBC Meeting of September 11, 2014*
Members Present:	Drs. Adam Clore, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan
Members Absent:	Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, James Sheets, and Jeffery Meier
Guests Present:	Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 28, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Clore, to approve the minutes of the August 28, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Pufall	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Boles	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Sigmund	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   There was no old business.

4. **New Business**

   a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
      - Dr. Jarosinski, #130139, was amended to include additional routes of administration.
      - Dr. Habelhah, #110232 and #140155, were amended to include additional lentiviral vectors and NF-kB activation inserts.
      - Dr. Adams, #120119, was amended to include a Co-PI and insulin-like growth factor receptor and a heterotrimeric G protein.
      - Dr. Harty, #110264, was amended to include expression plasmids carrying luciferase and ovalbumin.

   b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Lubaroff's amendment request to include a new Phase 1 study on his previously approved rDNARD #120347. This new study utilizes the same rDNA construct (Ad/PSA) and a similar number of injections and study subjects as the approved Phase 2 study. Dr. Kirchhoff explained that the previously-approved Ad/PSA vaccination study and the proposed Phase 1study differ only in the addition of the enzalutamide to the regimens that will be given to the study subjects. Dr. Kirchhoff also explained the rationale underlying the addition of enzalutamide, which is androgen pathway inhibitor, and commented on its success at suppression of metastatic prostate cancer in a large trial recently reported in the *New England Journal of Medicine*. The amendment request and new informed consent document were reviewed by the committee and no concerns were raised. Biosafety staff will review Appendix M and contact Dr. Lubaroff to ensure that all requirements for RAC review and communication with OBA have been completed. The members voted unanimously for approval.

The meeting adjourned at 4:07 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on September 25th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
UNIVERSITY
OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	September 25, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of September 25, 2014
Members Present:	Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Ms. Carol McGhan
Members Absent:	Drs. James Sheets, Jeffery Meier, and Haley Sinn
Guests Present:	Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on September 11, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the September 11, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	C. Stein	[redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	G. Richerson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Horswill	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	H. Habelhah	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Baker	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	G. Bishop	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Dunnwald	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Wilson	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

The second part of the meeting was open to the public.

3. **Old Business**

Ms. McGhan informed the committee about the status of the UI's response to the NIH's call to 'stand down' and complete an inventory of researchers' pathogen storage spaces. EHS plans to utilize the lists of organisms that EHS safety advisors have been obtaining from PIs over the last several years as they annually meet with each lab and update the inventory at that time. Beginning next month, EHS Biosafety staff will meet with each PI/lab manager where BSL2 (Risk Group 2) organisms are used/stored and perform a quality control check. This check will be used to determine if EHS' current inventory list is representative of what each PI actually has in his/her freezer.

Presuming this check will find the inventories are accurate, for the remainder of the labs as the safety advisors conduct annual audits they will ask several detailed questions related to lab inventories.

4. **New Business**

a) Ms. McGhan reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.

- Dr. Quelle, #130122, was amended to add new lab staff, a new AP number, and new route of administration.
- Dr. Chapleau, #140068, was amended to add two new synthetic inserts.
- Dr. Stapleton, #120021, was amended to include new vectors and inserts.
- Dr. Rutkowski, #140194, was amended to include a new host and use of naked plasmid rDNA.
- Dr. Abel, #140069, was amended to add new vectors, inserts and hosts, in addition to a Co-PI.

The meeting adjourned at 3:57 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on October 9th.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE
UNIVERSITY
OF IOWA

[redacted]

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	October 9, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of October 9, 2014
Members Present:	Drs. Lucy DesJardin, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Adam Clore, Leonard Duncan, Bradley Jones, and Jeffery Meier
EHS Staff Members Present:	Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:40 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on September 25, 2014**
   No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Sheets, to approve the minutes of the September 25, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with #140242 and #140245 rDNARDs and will abstain during the votes. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	B. Jones	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	J. Freeman	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	P. Sinn	[redacted]

- [redacted]

[redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	**PI**	**rDNA Registration Document Title**
[redacted]	P. Sinn	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Horswill	[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. McGowan	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	A. Kwitek	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

- [redacted]
- [redacted]
- [redacted]

- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	S. Gopishetty	[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
   There was no old business.

4. **New Business**

   a) Prior to today's meeting, Dr. Maes forwarded to committee members a document describing UI's response to NIH's stand down request. Biosafety staff described the measures taken to ensure training and programs are up-to-date and inclusive of all relevant information, as well as the activities that will be undertaken to ensure the biological agent inventories collected annually by the safety advisors are accurate. The committee members had no concerns with the draft.

   b) Dr. Kirchhoff discussed the membership of the committee and whether or not members preferred a formal or informal process of rotating off the committee. At this time no members responded that they would like to be rotated off the committee.

The meeting adjourned at 4:09 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on October 23rd.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date:	October 23, 2014
To:	Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject:	Minutes of the IBC Meeting of October 23, 2014
Members Present:	Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent:	Drs. Lucy DesJardin and Jeffery Meier
EHS Staff Members Present:	Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on October 9, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Clore, to approve the minutes of the October 9, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following four rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	J. Sebag	[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	K. Glenn	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	V. Lira	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

rDNA#	PI	rDNA Registration Document Title
[redacted]	R. Fisher	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff discussed the membership of the committee and asked if a specific term limit is appropriate. In the past, a term limit was established but members were difficult to find and subsequently train and the term limit was discarded. Since then members have been replaced as necessary. The committee determined that an informal process is preferable under which Dr. Kirchhoff will review the membership occasionally and contact members who do not participate in order to determine if they should be replaced.

4. New Business

a) Dr. Sinn reported on seven amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
   - Dr. Campbell, #120159, was amended to include two new inserts, furin and DOK7.
   - Dr. Weiss, #130162, was amended to include new promoters, use of the Flow Cytometry Facility and additional shuttle vectors.
   - Dr. McCray, #120062, was amended to update staff and include a Co-PI.
   - Dr. Harty, #110264, was amended to add additional vectors, including an MSCV vector.
   - Dr. Irani, #130158, was amended to include new inserts and TALEN vectors, additional staff and the creation of knockout mice.
   - Dr. Wilson, #140201, was amended to include additional routes of administration.
   - Dr. Banfi, #120191, was amended to include a microRNA as an insert.

b) Prior to today's meeting, Dr. Sinn forwarded to committee members the third quarter report from the Gene Transfer Vector Core. The committee had no concerns and voted unanimously for approval.

c) Dr. Sinn requested feedback from committee members on how to report required changes to the rDNARDs following consistency review by the IACUC administrator. The committee requested additional time to review new information in the rDNARD and determined that no changes should be made to the protocols after the Tuesday prior to the meeting. Ms. Dockstader will note all changes that are made to the rDNARDs after they are sent to members and send this worksheet to members on Tuesday before end of day; no subsequent changes to the rDNARDs will be made. Any outstanding issues that are not addressed in the worksheet will be discussed at the IBC meeting.

d) Ms. McGhan requested feedback from committee members on their preference for the new URL for the upcoming rDNA submission protocol. There were no concerns with using eIBC. Biosafety staff will inform RIS of the discussion.

The meeting adjourned at 4:10 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on November 6, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

THE UNIVERSITY OF IOWA

Environmental Health & Safety
100 EHS
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: November 6, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of November 6, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan, Bradley Jones, Jeffery Meier, and James Sheets

EHS Staff Members Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on October 23, 2014**
   No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. DesJardin, to approve the minutes of the October 23, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
   The rDNARD being considered was made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review; no conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

   The following one rDNARD was considered:

rDNA#	PI	rDNA Registration Document Title
[redacted]	M. Tanas	[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

The second part of the meeting was open to the public.

3. **Old Business**
None

4. **New Business**

a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
  - Dr. Perlman, #120125, was amended to include a tagged nucleocapsid protein from MHV as an insert.
  - Dr. Mahajan, #140058, was amended to include a Co-PI and add the E.coli strain, BL21.
  - Dr. Martin, #140082, was amended to include cell culture work with a replication defective MLV vector.
  - Dr. Campbell, #120159, was amended to update staff and include jugular as a route of administration.
  - Dr. Fisher, #140262, was amended to include additional inserts that will be administered to animals.

b) Prior to today's meeting, Dr. Sinn forwarded to committee members the report covering last July's [redacted] facility and their responses. Dr. Sinn and Ms. McGhan discussed the inspection report and the committee had no concerns with the report or the responses. Ms. McGhan made a motion, seconded by Dr. Clore, to approve the report. The members voted unanimously for approval.

The meeting adjourned at 3:40 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on November 20, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee